ATTACHMENT 59

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE COMPANY, INC., Plaintiff/Counterclaim Defendant, v. INTUITIVE SURGICAL, INC., Defendant/Counterclaim Plaintiff.	Case No. 3:21-cv-03496-VC

EXPERT REPORT OF CHRISTY FOREMAN, MBE

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January 18, 2023

This report contains confidential material and is subject to the order governing the production, exchange and filing of confidential information in this matter.

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I. Qualifications

1. I graduated from The Catholic University of America with Bachelor's and Master's degrees in Biomedical Engineering. While I was pursuing my undergraduate degree, I began working at the Naval Medical Research Institute (NMRI). There, I supported the research activities designed to evaluate the physiologic effects of non-freezing cold injury as well as the research activities evaluating short term memory decrements in cold weather operations in humans and animals. I worked there for a total of seven years before I departed to work for the US Food and Drug Administration (FDA) in 1996.

2. I started at FDA as a reviewer in the Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), Division of Cardiovascular, Respiratory, and Neurological Devices in the Anesthesiology and Defibrillator Devices Group. While working as a reviewer, I reviewed a wide variety of devices including ventilators, hyperbaric chambers, multi-parameter monitors, pulse oximeters, automated external defibrillators and implantable defibrillators, including the biventricular (cardiac resynchronization therapy) defibrillators designed to treat heart failure, a novel, brand-new indication at the time.

3. As a lead reviewer, I reviewed hundreds of 510(k) submissions, Investigational Device Exemption (IDE) Submissions, and Premarket Approval (PMA) Application Submissions. I also served as a signatory reviewer, reviewing the work of others as a technical expert. I was appointed as the FDA representative on voluntary consensus standards such as the National Fire Protection Association (NFPA) standard on Hyperbaric and Hypobaric Facilities, American Society of Mechanical Engineers (ASME) standard on Pressure Vessels for Human Occupancy, and the American Society for Testing and Materials (ASTM) G175 Standard

Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Pressure Regulators Used for Medical and Emergency Applications. These standards are developed in conjunction with industry, academia, and health care providers to set forth requirements for safe design practices as well as test methods for evaluating medical device designs.

4. In 2000, I was selected for a highly competitive FDA Leadership Development Program. Over the course of the program, in addition to training opportunities, I completed several detail assignments further expanding my FDA knowledge base. The detail assignments included a branch chief position in the Minnesota District Office, where I oversaw the Import Operation activities as well as participated in inspections of drug, device, and food manufacturers as well as bioresearch monitoring inspections. I also had an assignment at Health Canada in the Medical Devices Bureau to compare and contrast the different regulatory processes between the US and Canada. I also completed an assignment in the Office of Science, Communication and Coordination in the Office of the Commissioner where I served as the executive secretary for the Science Board, an advisory committee designed to advise the Commissioner of various scientific topics.

5. My final detail assignment was in CDRH's Office of Compliance (OC) in the Division of Enforcement B as the Deputy Division Director. The division was responsible for the compliance oversight of cardiovascular, neurology, orthopedic, physical medicine, anesthesiology, and radiology devices, as well as electronic products. This detail lasted 10 months until I accepted a permanent position as the branch chief for the Orthopedic, Physical Medicine, and Anesthesiology Devices Branch in OC in 2001. After a year in the position, I was

selected in 2002 for the permanent Deputy Division Director position in OC where I had previously served on detail.

6. While working in OC, I was responsible for the oversight of inspection reviews, PMA quality system reviews, 30-day notice reviews, recalls, warning letters, seizures, injunctions, and civil money penalties. In this position, I not only oversaw the review activities, but developed policy in these areas as well. I routinely provided training for industry at AdvaMed workshops, AAMI Quality System Training Courses as well as participated in numerous conferences where I was invited to speak. I was responsible for overseeing many enforcement actions including civil money penalties for mammography facilities, a seizure, and injunction for a tissue-based heart valve and valve conduit as well as injunctions for an automated external defibrillator, an orthopedic implant, and x-ray surgical imaging systems. I also served as an FDA expert witness in a criminal case against an implantable defibrillator and pacemaker manufacturer.

7. In 2008, I returned to ODE as the Deputy Office Director for Science and Engineering reviews. In this role I served as the chief scientific officer for ODE and oversaw the regulatory policies associated with 510(k), PMA, HDE, IDE, de novo and 513(g) programs as well as combination products as well as provided office- level review and sign-off for guidance documents, de novo submissions and 513(g) submissions. In this role, the area of oversight included surgical devices including surgical robots.

8. In 2010, I began serving as the Office Director for ODE. In that role, I oversaw a staff of 500+ scientists and clinicians conducting the regulatory review of applications including 510(k)s, PMAs, IDEs, HDEs, pre- submissions, Product Development

Protocols, De Novos and 513(g)s, as well as consults for combination products in NDAs and BLAs and decided all office level appeals. I provided the final sign-off for first of a kind Premarket Approval Applications. I also participated in user fee negotiations with industry, implemented the user fee commitments into the regulatory review programs and implemented new legislation (FDASIA). In this role, the area of oversight included surgical devices including surgical robots.

9. In 2014, I joined the FDA's newest Center, the Center for Tobacco Products to help develop new regulations and regulatory programs to help implement the Family Smoking Prevention and Tobacco Control Act (FSPTCA), also known as the Tobacco Control Act which gave FDA the authority to regulate tobacco. The law was largely based on the medical device provisions of the Federal Food, Drug, and Cosmetic Act. I was recruited for my significant experience with the medical device programs. There, I worked on foundation regulations such as the tobacco product manufacturing regulation as well as implemented new enforcement programs such as the No-Tobacco-Sale Order (NTSO) program. I participated in inspections of tobacco product manufacturers as a subject matter expert. I also developed and oversaw enforcement actions for egregious violators of the Tobacco Control Act. I was involved in the pursuit of thousands of civil money penalty cases and over 100 NTSO cases during my time at CTP. My experience with these cases affords my expertise in the type and quality of evidence that is needed to support an FDA enforcement action.

10. In 2018, I left CTP to join Biologics Consulting as a Senior Consultant. In my role as a Senior Consultant, I advise clients on short and long term regulatory strategies for medical devices and combination products, assist in the development of Quality Systems,

prepare medical device regulatory submissions, including 510(k)s, PMAs, HDEs, RFDs, 513(g)s, pre-submissions, and IDEs, represent clients in interactions with FDA, assist clients in the preparation for Advisory Panel meetings and provide in-house training on FDA regulatory issues and new policy developments. I also provide expert services to litigants.

11. Additionally, I am an adjunct lecturer at The Catholic University of America, where I teach a graduate level course entitled Medical Device Design and Regulation in the Biomedical Engineering Department.

12. A copy of my curriculum vitae is attached as Appendix A.

II. Assignment, Summary of Opinions and Materials Considered

13. I have been retained by defendant Intuitive Surgical, Inc. ("Intuitive") to provide my expert opinions on certain FDA-related matters in this litigation.

14. The professional fee charged for my consulting time by my employer, Biologics Consulting, is $525 per hour. I am a salaried employee of Biologics Consulting. My compensation is not dependent on my opinions in, or the outcome of, this litigation. I have testified as an expert in the preceding four years in the following matters: *Tonya Brand v. Cook Medical, Inc.*, Deposition: July 2018; Trial: January 2019, Southern District of Indiana No. 1:14-cv-06018-RLY-TAB; *Karen Richards v. Ethicon, Inc. and Johnson & Johnson*, Trial: October 2022, Eastern District of Texas No. 5:21-cv-92-RWS; *Selex Galileo, Inc. v. Nomir Medical Technologies, Inc.*, International Center for Dispute Resolution, No. 01-17-0003-0930.

15. My opinions and analyses in this report are based on my review and evaluation of the materials listed in Appendix B. In addition, my opinions are based on my knowledge and experience of FDA regulation of medical devices, including all applicable laws,

regulations, guidance, and policies. I reviewed and assessed the documents in a similar manner as I would have while employed at the FDA and as I do now as a medical device consultant. I did not rely on any commercial, confidential, or trade secret information obtained during my employment at FDA in forming my opinions.

16. Based on the analyses developed in the body of my report, I conclude:

a. Remanufacturing medical devices is a manufacturing activity, which is subject to FDA regulatory requirements, including premarket notification, registration, recall, medical device reporting, unique device identification, and postmarket surveillance among others.

b. EndoWrist instruments were cleared by FDA as limited use devices, and efforts to remove or extend the usage limitation by companies other than the original equipment manufacturer (OEM) constitute remanufacturing activities.

   i. FDA cleared EndoWrist instruments as limited-use devices.

   ii. FDA has acknowledged the limited use nature of EndoWrist instruments in communications to third parties.

   iii. Objective and publicly available evidence demonstrates that FDA has determined that removing or extending the usage limitation on EndoWrist instruments is a manufacturing activity, and as such, it requires 510(k) clearance.

      1. FDA has classified remanufactured EndoWrists as Class II devices, assigned them a unique procode, and indicated that they require 510(k) clearance.

2. Congress also reached the same conclusion for a similar industry and activity – reprocessing – and amended FDA's governing statute to define premarket requirements for the reprocessors of devices labeled for single use.

iv. Third parties engaging in extending or resetting the lives of EndoWrist instruments are remanufacturers under existing FDA regulation. Therefore, they were required to obtain 510(k) clearance.

1. The activities that the third parties undertake to extend the usage limits significantly change the performance specifications of EndoWrist instruments.
2. The activities that the third parties undertake to extend the usage limits significantly change the safety specifications of EndoWrist instruments.
3. The third parties are introducing new devices into interstate commerce, which makes their activity subject to FDA requirements.
4. The third parties' arguments that they are not remanufacturers are incorrect.

c. FDA communicated to certain third parties that their activities constituted remanufacturing.

d. Intuitive has acted in accordance with FDA's requirements for the marketing and sale of its devices and has not unreasonably interpreted FDA's existing regulations and guidance.

i. Intuitive's marketing and sale of EndoWrist instruments with usage limits is consistent with FDA's regulatory requirements.

ii. Intuitive's cybersecurity measures are consistent with FDA expectations for devices that are vulnerable to cybersecurity threats.

iii. Intuitive's internal conduct does not contradict applicable FDA regulations and guidance, nor does it negate the duty of third-party companies to comply with existing FDA regulations and guidance.

III. Medical Device Regulatory Overview

A. FDA Regulatory Authority

1. Statutory Authority

17. The Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices, and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.[1]

18. FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by

[1] FDA Mission Statement, available at https://www.fda.gov/about-fda/what-we-do (last accessed Jan. 17, 2023).

helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.[2]

19. The mission of FDA is to enforce laws enacted by Congress and regulations established by the Agency to protect the consumer's health, safety, and pocketbook. Its primary focus is the enforcement of the Federal Food, Drug, and Cosmetic Act (the "FD&C Act" or "Act"), the basic food and drug law of the U.S. The law is intended to, in part, assure, that drugs and devices are safe and effective for their intended uses and that all labeling and packaging is truthful, informative, and not deceptive.[3]

20. As such, the FDA is the federal entity responsible for providing regulatory oversight of the manufacturing, sale, and distribution of medical devices in the United States. FDA's authority comes from the Act, as amended by the Medical Device Amendments of 1976 and subsequent amendments. The Center for Devices and Radiological Health (CDRH), a Center located within the FDA, has primary responsibility for implementing these authorities.

2. Regulation

21. The scope of FDA's regulatory authority is very broad, and its responsibilities are closely related to those of several other government agencies.[4] Federal regulations are either required or authorized by statute.

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[2] Ibid.

[3] FDA, FDA Related Laws, Regulations, and Guidances, https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/fda-related-laws-regulations-and-guidances (last accessed Jan. 17, 2023); FDA, Federal Food, Drug, and Cosmetic Act (FD&C Act), https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act (last accessed Jan. 17, 2023).

[4] FDA, Regulatory Information, https://www.fda.gov/regulatory-information (last accessed Jan. 17, 2023).

22. FDA enacts regulations that interpret the FD&C Act and related statutes. FDA regulations are collected in the Code of Federal Regulations (CFR), Section 21, and published in the Federal Register, as required by law.

3. Guidance Documents

23. FDA's regulatory authority begins with the law or statute that is passed by Congress, which is then refined and expanded upon in regulation. FDA also issues "guidance documents," which are intended to provide FDA's current thinking on a topic.

24. In 1997, FDA published its policy on ''Good Guidance Practices'' (GGP's), which sets forth the agency's policies and procedures for the development, issuance, and use of guidance documents.[5] As to the legal effect of guidance documents, the policy noted that while guidance does not bind the agency or the industry:

> *[T]hey explain how the agency believes the statutes and regulations apply to certain regulated activities. However, because a guidance document represents the agency's current thinking on the subject addressed in the document, FDA's decision makers will take steps to ensure that their staff do not deviate from the guidance document without appropriate justification and appropriate supervisory concurrence.*[6]

25. The policy provided some standard language that is included at the beginning of all subsequently issued FDA guidance:

> *This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and*

[5] 62 Fed. Reg. 8961 (Feb. 27, 1997).

[6] Ibid. at 8963.

> *regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance*.[7]

26. In 2000, this policy was formalized into regulation.[8]

27. Guidance documents are a critical part of the premarket review program, including the 510(k) program. Example of the types of guidance documents that FDA issues include:

- program specific guidance documents, such as the 510(k) Program which described how to evaluate substantial equivalence,[9] the 510(k) Format which discusses the format and content for 510(k) submissions,[10] and the Modifications guidance document which describes when modifications require the need for a new 510(k) submission[11] as well as a specific modifications guidance for software changes;[12]

[7] For example, this language appears in the FDA guidance document, "Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications)" (Aug. 30, 2019) (originally issued Mar. 28, 2012), available at https://www.fda.gov/media/99769/download (last accessed Jan. 17, 2023).

[8] 21 CFR § 10.115.

[9] FDA, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" (July 28, 2014), available at https://www.fda.gov/media/82395/download (last accessed Jan. 17, 2023).

[10] FDA, "Format for Traditional and Abbreviated 510(k)s" (Sept. 13, 2019) (originally issued Aug. 12, 2005), available at https://www.fda.gov/media/130647/download (last accessed Jan. 17, 2023).

[11] FDA, "Deciding When to Submit a 510(k) for a Change to an Existing Device" (Oct. 25, 2017) (originally issued Jan. 10, 1997), available at https://www.fda.gov/media/99812/download (last accessed Jan. 17, 2023).

[12] FDA, "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (Oct. 25, 2017), available at https://www.fda.gov/media/99785/download (last accessed Jan. 17, 2023).

- device specific guidance documents, such as the guidance for Intravascular Filters.[13]; and

- cross-cutting guidance documents. The 510(k) Format guidance recommends that a 510(k) submission contain standardized sections on the following topics: Labeling, Sterilization and Shelf Life, Biocompatibility, Software, and Electromagnetic Compatibility and Electrical Safety. These sections have one or more cross-cutting guidance documents associated with it that apply equally to 510(k)s as well as PMAs.

28. While adherence to the recommendations in guidance documents is not strictly required, in practice FDA expects manufacturers to follow them closely or to have a very good justification or rationale for not following the identified recommendations.[14]

B. Medical Device Classification

29. FDA, by law, uses a risk-based classification scheme for products that meet the legal definition of a medical device.

30. The Act defines a device[15] as:

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—
>
> (A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
>
> (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

[13] Due to the large number of device types, FDA has not issued device specific guidance documents for the majority of device types.

[14] Similarly, while draft guidance documents do not have the force of final guidance documents, draft guidance documents are instructive and, when finalized, would represent FDA's current thinking on a topic.

[15] FD&C Act, 21 U.S.C. § 321(h)(1).

> (C) intended to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

31. The Act establishes three classes of medical devices based on the risk of the device and provides for regulatory controls that are commensurate with the risk and the ability to control that risk.[16]

32. Class I devices are the lowest risk devices, for which "general controls" are adequate to provide a reasonable assurance of safety and effectiveness.[17]

33. General controls include a prohibition against adulteration or misbranding, registration of device manufacturing facilities, listing of the device types, records and reports (including adverse event reports, device tracking, if ordered, unique device identification and reports of corrections or removals), repair, replacement and refund, as well as provisions regarding banned devices and compliance with good manufacturing practices (unless exempt by regulation). Most Class I devices are exempt from any premarket notification requirements.[18]

34. Examples of Class I devices include canes, crutches, patient exam gloves, bandages and scalpels.

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[16] 21 U.S.C. § 360c(a).

[17] 21 U.S.C. § 360c(a)(1)(A).

[18] FDA, Regulatory Controls, https://www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls (last accessed Jan. 17, 2023).

35. Class II devices are moderate risk devices, for which there is sufficient information to establish special controls to provide a reasonable assurance of safety and effectiveness. These devices cannot be classified into Class I because general controls by themselves are insufficient to provide such an assurance.[19]

36. Special controls can include performance standards, postmarket surveillance, patient registries, special labeling requirements, premarket data requirements and guidelines.[20]

37. Class II devices are generally subject to FDA review and clearance through the submission of a "premarket notification," also known as a 510(k).[21] The 510(k) notification for a Class II device must demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent in terms of intended use and technological characteristics to another Class II (moderate risk) device and comply with any special controls, if promulgated. This process is sufficient, in the FDA's view, to provide a reasonable assurance of safety and effectiveness for that device type.[22] Therefore, each substantially equivalent decision, while not an independent determination of reasonable assurance of safety and effectiveness like that which is required for a premarket approval for a Class III device (discussed below), can still be considered a determination of reasonable assurance of safety and effectiveness because it

[19] 21 U.S.C. § 360c(a)(1)(B).

[20] FDA, Regulatory Controls, https://www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls (last accessed Jan. 17, 2023).

[21] 21 U.S.C. § 360c(a)(1)(B).

[22] FDA, Premarket Notification 510(k), https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k (last accessed Jan. 17, 2023).

leverages the body of knowledge that allowed for the device to be classified as Class II. The 510(k) notification is discussed in more detail in Section III.C.

38. Examples of Class II devices include ventilators, hip implants with metal/polymer bearing surfaces, soft contact lenses, X-ray equipment, MRI devices, infusion pumps, biopsy devices, and surgical instruments for use with specific devices such as surgical mesh for stress urinary incontinence.

39. Class III devices are the highest risk or most novel device types, for which general and special controls are not adequate to provide a reasonable assurance of safety and effectiveness.[23]

40. Because they present the highest risk, they are generally subject to FDA review and approval of a premarket approval application, commonly referred to as a PMA, which requires an independent demonstration of a reasonable assurance of safety and effectiveness, based on valid scientific evidence.[24]

41. Examples of Class III devices include implantable defibrillators, drug-eluting coronary stents, implantable diaphragmatic/phrenic nerve stimulators, and mechanical heart valves.

42. FDA, with the assistance of Congressionally mandated medical advisory panels, has established classifications for approximately 1,700 different generic types of devices and grouped them into 16 medical specialties referred to as panels.[25] Each of these generic

[23] 21 U.S.C. § 360c(1)(C).

[24] Ibid.

[25] FDA, Classify Your Medical Device, https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device (last accessed Jan. 17, 2023).

types of devices is assigned to one of the three regulatory classes based on the level of control necessary to reasonably assure the safety and effectiveness of the device. Information about the device types that have been classified can be found in 21 Code of Federal Regulations (CFR) §§ 862 – 892, or by searching FDA's classification database.[26]

43. In addition to the classifications in the Act and the regulations, FDA also identifies device types using product codes (also known as "procodes"). FDA assigns a unique 3-letter product code for each generic type of device, whether it has been formally classified by FDA or not. One classification regulation may include multiple procodes.[27]

44. For all classes, FDA's standard is the same: there must be "reasonable assurance" that the device is safe and effective. For class I devices, general controls alone provide a reasonable assurance of safety and effectiveness; for Class II devices, general plus special controls provide a reasonable assurance of safety and effectiveness; for class III devices, premarket approval provides a reasonable assurance of safety and effectiveness. While 510(k) clearance is a less rigorous process than premarket approval, that is because it only applies to device types that the FDA and its medical panels have found to present moderate risks.

45. It is important to note that FDA is responsible for assigning the appropriate regulatory classification and regulatory submission type. FDA selects an appropriate pathway after the agency reviews the relevant known risks and benefits and determines if those known risks can be adequately controlled by regulatory tools such as

[26] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm

[27] FDA, "Medical Device Classification Product Codes" (Apr. 11, 2013), available at https://www.fda.gov/media/82781/download (last accessed Jan. 17, 2023).

general and special controls. Based on that review, FDA then establishes the regulatory classification, which determines the required regulatory pathway that manufacturers must follow.

46. The use of the 510(k) pathway as dictated by FDA is not a "bypass" of the premarket approval process nor is it a temporary status. It is what FDA requires for device types that present a moderate risk.

47. You would not have a circumstance where a high-risk device has been placed into Class III by FDA and requires the submission of a PMA, yet a manufacturer would opt to submit a 510(k) rather than a PMA, or vice versa.

48. FDA decides whether the manufacturer must use 510(k) clearance or must instead seek premarket approval. The manufacturer does not get to choose the application pathway that it prefers but must adhere to the regulatory pathways that FDA establishes for each device type.

C. Premarket (510(k)) Notification

49. A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device. Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval application (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and does not exceed the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9). Before marketing a device, each submitter must receive an order, in the form of a letter,

from FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. This order "clears" the device for commercial distribution.

1. Background on 510(k) Notification

50. As discussed in Section III.B., certain devices (Class II) are subject to the premarket (510(k)) notification requirement.

51. Devices that are subject to the premarket notification requirement cannot be legally marketed in the United States until FDA has issued an order finding that the device is "substantially equivalent (SE)" to a "predicate" device.

52. Under the FD&C Act, "each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary . . . (in such form and manner as the Secretary shall by regulation prescribe)-–

> (1) the class in which the device is classified under section 360c of this title or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and
>
> (2) action taken by such person to comply with requirements under section 360d or 360e of this title which are applicable to the device."[28]

53. A predicate device is a legally marketed device to which a new device may be compared for a determination regarding substantial equivalence. It could be a device

[28] 21 U.S.C. § 360(k).

that was legally marketed prior to May 28, 1976, or a device which has been reclassified from Class III to Class II or Class I, or a device which has been found to be substantially equivalent through the 510(k) premarket notification process.[29]

54. A premarket notification submission is also required when a manufacturer makes significant changes or modifications to a device that it has already introduced or plans to reintroduce into commercial distribution.[30]

55. 21 CFR 807.81(a)(3) states that a premarket notification 510(k) submission is required when the device "is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. A significant change or modification requiring a premarket notification includes "a change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process."[31]

56. FDA notes in the 510(k) Modifications guidance: "To determine whether a change or modification could significantly affect the safety or effectiveness of a device, the manufacturer should first conduct a risk-based assessment, using the guidance below, of whether the change could significantly affect the device's safety or effectiveness, either positively or negatively. This risk-based assessment should identify and analyze all new risks

[29] 21 CFR § 807.92(a)(3).

[30] 21 CFR § 807.81(a)(3).

[31] 21 CFR § 807.81(a)(3)(i).

and changes in existing risks resulting from the device change, and lead to an initial decision whether or not submission of a new 510(k) is required."[32]

2. Substantial Equivalence

57. FDA has issued regulations[33] and guidance[34] specifying the contents of a 510(k) notification. The 510(k) submission is not a form, but a compilation of specific information regarding a medical device to demonstrate the equivalence of the new device to a predicate device. In brief, the submitter must provide a description of the device, a comparison to the predicate device(s), and data that demonstrate that the device is substantially equivalent. The data can include bench testing as well as animal or clinical data.

58. For FDA to determine that a new device is substantially equivalent to a predicate device, FDA must determine that the device:

> (i) has the same technological characteristics as the predicate device, or
>
> (ii)(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary that demonstrates that the device is as safe and effective as a legally marketed device, **AND**

[32] FDA, "Deciding When to Submit a 510(k) for a Change to an Existing Device," at 8.

[33] 21 CFR § 807.87.

[34] FDA, "Format for Traditional and Abbreviated 510(k)s" (Sept. 13, 2019) (originally issued Aug. 12, 2005), available at https://www.fda.gov/media/130647/download (last accessed Jan. 17, 2023).

> (II) does not raise different questions of safety and effectiveness than the predicate device.[35]

59. The term "different technological characteristics" means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.[36]

60. The same definitions of safety and effectiveness apply to all devices, regardless of class:

> *There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks.*[37]
>
> . . .
>
> *There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.*[38]

61. As explained earlier, for both safety and effectiveness, the regulatory standard is "reasonable assurance." At the time of the initial Medical Device Amendments, it

[35] 21 U.S.C. § 360c(i)(1)(A) (emphasis added).

[36] 21 U.S.C. § 360c (i)(1)(B).

[37] 21 CFR § 860.7(d)(1).

[38] 21 CFR § 860.7(e)(1).

was noted that this standard is "*predicated upon the recognition that no regulatory mechanisms can guarantee that a product will never cause injury, or will always produce effective results. Rather, the objective of the legislation is to establish a mechanism in which the public is afforded reasonable assurance that medical devices are safe and effective.*"[39]

62. FDA issued a final guidance entitled "*The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] Guidance for Industry and Food and Drug Administration Staff"* on July 28, 2014.[40] This guidance superseded FDA's longstanding "*Guidance on the CDRH Premarket Notification Review Program, 510(k) Memorandum K86-3*," dated June 30, 1986. Both guidance documents provided guidance on how to determine if a medical device is substantially equivalent. The same logic and questions apply in both guidance documents. A main difference in the newer guidance is that it provides greater clarity on the appropriate use of multiple predicates by including the concept of a reference device. This difference between the two guidance documents has no bearing on this case. A flowchart was also included to serve as an aid in making the SE determination.

63. If FDA determines that a new device is substantially equivalent to a predicate device, it will issue a letter known as a "Substantially Equivalent" or "SE" Letter allowing the device to be marketed. The device is then said to be "cleared."[41]

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[39] H.R. Rept. 94-853, at 15 (Feb. 29, 1976).

[40] Available at https://www.fda.gov/media/82395/download (last accessed Jan. 17, 2023).

[41] There is a regulatory distinction between "clearance" and "approval", but people commonly confuse the two terms because "clearance" today requires that FDA grant permission to market the device. It is not uncommon to see references to devices cleared through the 510(k) process as being "FDA Approved." 21 CFR § 807.97 indicates that any representation that creates an impression of official approval of a device because of complying with the premarket

64. FDA will post the clearance and provide a copy of the "SE Letter," "Indications for Use Form" and "510(k) Summary" (if available) on the FDA website.[42]

3. Deficiency Letters

65. During the course of a review, when FDA has questions or concerns about an application, it can ask for additional information. This is done typically in one of two ways. FDA can ask interactive questions by email where the FDA review clock is not stopped and the sponsor has a short time to respond or FDA can send a deficiency letter that places the submission on hold and the sponsor has a longer timeframe to respond. FDA typically issues only one deficiency letter during the review process, however, certain circumstances may allow for the issuance of a second letter.

66. In a deficiency letter, FDA will distinguish between major deficiencies, which, if not adequately resolved, may preclude a favorable decision on the marketing application, and minor deficiencies, which can be resolved in a straightforward manner but need to be addressed to meet regulatory requirements or to prevent potential misbranding or adulteration.

IV. Opinions and Bases for Opinions

67. In formulating my opinions, which apply the appropriate regulatory framework as discussed above, I have reviewed publicly available information as well as the documents produced through discovery. I conducted a thorough review of relevant information

notifications regulations is misleading and constitutes misbranding. However, FDA currently does not routinely enforce this regulation absent other violations.

[42] Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm.

necessary to develop my opinions regarding the activities at issue. The methods that I used are similar to the methods that I have employed throughout my career, including those methods that I used as a reviewer, manager and senior manager at the Food and Drug Administration and as a consultant to medical device companies.

A. Opinion 1 – Remanufacturing medical devices is a manufacturing activity, which is subject to FDA regulatory requirements, including premarket notification, registration, recall, medical device reporting, unique device identification, and postmarket surveillance among others.

68. Remanufacturing is clearly defined by FDA in existing regulations.

69. Plaintiff and the relevant third parties in this case have suggested that the definition of "remanufacturing" is a "murky area" because FDA has not published final guidance on all distinctions between remanufacturing and servicing.[43] But FDA's definition of remanufacturing has been clear since the promulgation of 21 CFR 820 in 1996,[44] and there is no doubt that a party that engages in the activities described in the regulation is a remanufacturer.

70. 21 CFR Part 820 (the Quality System Regulation) (the "QSR") provides the FDA regulatory requirements for good manufacturing practices for medical devices. FDA explained: "The provisions of this part shall be applicable to any finished device as defined in this part, intended for human use, that is manufactured, imported, or offered for import in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico."[45]

[43] Intuitive-00706083, at -6086.

[44] 61 Fed Reg. 52602 (Oct. 7, 1996).

[45] 21 CFR § 820.1(a)(2).

71. The QSR defines both "manufacturer" and "remanufacturer":

> (o) A manufacturer is any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.
>
> . . .
>
> (w) A remanufacturer is any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.[46]

72. When FDA proposed its revisions to 21 CFR 820,[47] it solicited comments on the definitions published in the proposed rule. The preamble to the final rule (Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation[48]), specifically the Agency's Response 28, discusses those comments as well as the Agency response to those comments:

> Several comments in response to the proposed definition of ''manufacturer'' stated that refurbishers and servicers should be added to the definition of a ''manufacturer.'' Other comments recommended adding the term ''remanufacturer.'' Other comments requested deletion of contract sterilizers, installers,

[46] 21 CFR § 820.3.

[47] Under Section 520(f) of the Act, FDA issued a final rule in the Federal Register of July 21, 1978 (43 FR 31 508), prescribing Current Good Manufacturing Practice (CGMP) requirements for the methods used in, and the facilities and controls used for the manufacture, packing, storage, and installation of medical devices. This regulation became effective on December 18, 1978, and is codified under 21 CFR part 820. In November 1993, the agency issued its proposed revisions to the regulation. 58 Fed. Reg. 61952 (Nov. 23, 1993).

[48] 61 Fed. Reg. 52602 (Oct. 7, 1996).

> specification developers, repackagers, relabelers, and initial distributors from the definition.
>
> One comment stated that the phrase ''processes a finished device'' should be explained in the definition of manufacturer.
>
> FDA's Compliance Policy Guide (CPG) 7124.28 contains the agency's policy regarding the provisions of the act and regulations with which persons who recondition or rebuild used devices are expected to comply. This CPG is in the process of being revised in light of FDA's experience in this area. . . . Because of a number of competitive and other issues, including sharply divided views by members of the GMP Advisory Committee at the September 1995 meeting, FDA has elected to address application of the CGMP requirements to persons who perform servicing and refurbishing functions outside the control of the original manufacturer in a separate rulemaking later this year, with another opportunity for public comment.
>
> FDA agrees that the term ''remanufacturing'' should be added to the definition of ''manufacturer'' and has separately defined the term. A remanufacturer is defined as ''any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.'' [49]

73. This discussion in the preamble signifies that thought was specifically given to the inclusion of remanufacturing as part of the definition of "manufacturer," including developing a separate definition for the new term "remanufacturer," and that this was supported by comments that were received on the proposed rule.

[49] 61 Fed. Reg. 52602 at 52609 (Oct. 7, 1996). FDA solicited public comments on the proposed rule until October 23, 1995. Approximately 280 separate individuals or groups commented on the proposal published in the Federal Register of November 23, 1993, and approximately 175 separate individuals or groups commented on the Working Draft that was announced in a notice of availability published in the Federal Register on July 24, 1995.

74. Phillips suggests that the supposed "lack of clarity" related to FDA's definition of "refurbishing" or "servicing" is of import in this case.[50] However, where a party engages in the activities listed in the definition of "remanufacturer," there can be no doubt that the party is a remanufacturer and is subject to the associated regulatory requirements.

B. Opinion 2 – EndoWrist instruments were cleared by FDA as limited use devices, and efforts to remove or extend the usage limitation by companies other than the original equipment manufacturer (OEM) constitute remanufacturing activities.[51]

1. FDA cleared EndoWrist instruments as limited use devices.

75. The usage limitation is an essential safety and performance specification for the EndoWrist instruments. Intuitive engaged in extensive life and performance testing, which was submitted to FDA, to provide FDA a reasonable assurance of the safety and the effectiveness of the device.

76. The device descriptions in both K965001 and K990144, the earliest 510(k) submissions for the da Vinci Surgical System and its instruments, state that the instruments are "resposable" and "limited use."[52] The fact that the "indications for use" in the 510(k) summaries do not specifically state that EndoWrist instruments are subject to limited use makes no difference, as the usage limitations were clearly indicated in the device descriptions and elsewhere in the 510(k) submission.

[50] Opening Expert Report of Philip J. Phillips (Dec. 2, 2022) ("Phillips Report") § III.F, ¶ 114.

[51] Efforts to remove or extend the usage limitation by the OEM, Intuitive, constitute manufacturing and are also subject to premarket requirements.

[52] Intuitive-00691660; Intuitive-00692314.

77. In order to understand FDA's clearance of EndoWrist instruments as limited use devices, it is helpful to look at certain premarket submissions for EndoWrist instruments.

a) K990144

78. The original 510(k) for Intuitive's EndoWrist family of instruments as well as subsequent 510(k)s demonstrate that the instruments were cleared by FDA as limited use devices.

79. On January 18, 1999, Intuitive submitted a 510(k) for additional instruments to be used with the Intuitive Surgical Endoscopic Instrument Control System (Model IS1000), including scissors, scalpels, forceps, clip applier, electrocautery and accessories, pick-ups and needle drivers/holder.[53] The trade name listed for the instruments in this 510(k) was Intuitive Surgical™ Instruments/Accessories: "Resposable" (limited reuse) Endoscopic Instruments.

80. In its Substantial Equivalence Comparison/Rationale, Intuitive explained: "Intuitive Surgical has worked hard to reduce risks associated with the use of the Endoscopic Instrument Control System to an absolute minimum. This has been done through extensive failure modes effects and criticality analysis (FMECA) . . . and extensive fail-safe and redundant design assuring no uncontrolled instrument movement. This fail-safe design has been verified and validated through both in vitro and in vivo testing including more than 170 clinical procedures to date."[54]

[53] Intuitive-00692310.

[54] Intuitive-00692321, at -2324-25.

81. Intuitive provided the instrument and accessory physical specifications to FDA, and explained that "Tool ID electronics . . . provide electronic recognition of the tool, and store number of uses remaining in memory."[55]

82. Furthermore, "[t]he system electronics is responsible for performing all telepresence control functions and video processing functions of a sophisticated electro-mechanical system in a surgical environment. Additionally, and of at least equal importance, it is responsible for detecting system faults and taking such protective actions as necessary so as to ensure both patient and operating room staff safety under all conceivable failure conditions."[56]

83. FDA solicited additional information from Intuitive on the limited use nature of its instruments as part of the 510(k) review. Among FDA's requests was a "summary of your validation of the reuse instructions for the 'resposables'" and "a mechanism for assuring that single use instruments such as scalpels and electrocautery will not be confused with 'resposable' and will not be reused."[57]

84. Intuitive explained in Section 3.8 of the Device Description, "Summary of Pre-Clinical Studies," the testing done to ensure mechanical reliability. Intuitive explained, "*In vitro* component and sub-system cycle life and durability testing has been performed. This work has included mechanical arms and instruments and has demonstrated reliability consistent with product labeling and use recommendations. Instruments are programmed to "expire" and not

[55] Intuitive-00692451, at -2454.

[56] Intuitive-00692433, at -2436.

[57] Intuitive-00692185, at -2205-06.

be useable after a predetermined amount of usage in order to assure reliable operation and the absence of "wear out."[58]

85. On July 11, 2000, FDA cleared the instruments, writing, "Based upon the product technical information, intended use, and performance information provided in the pre-market notification, the Intuitive Surgical Endoscopic Instrument Control System has been shown to be substantially equivalent to currently marketed predicate devices."[59]

b) K013416

86. On October 12, 2001, Intuitive submitted another 510(k) for certain EndoWrist instruments, including endoscopic forceps, graspers, needle drivers, scissors, scalpels (K013416). In the 510(k) Summary, Intuitive explained: "The subject device(s) consist of a family of endoscopic instruments with either grasping or cutting and effectors to be used with the Intuitive Surgical da Vinci Endoscopic Instrument Control System. . . . The instruments are re-usable (for a limited number of uses), are provided non-sterile, and must be cleaned and sterilized before use (pre-vacuum autoclave). . . . The instruments are provided for a limited number of uses to ensure reliability and consistent performance, and have non-volatile 'add-only' memory that the Instrument Control System decrements after each use."[60]

87. Intuitive also provided testing data in this submission. It explained that standard bench testing data was performed for each of the subject EndoWrists as part of

[58] Intuitive-00692611, at -2634.

[59] Intuitive-00691203, at -1204.

[60] Intuitive-00515501, at -5508-09.

standard verification and validation testing conducted prior to commercial introduction.[61] The testing included a life cycle test: "Perform range of motion cycles on each wrist axis based on expected range of motion during surgical procedures to determine that the cables don't derail or fray, that the pulley turns, and that the wrist unit functions correctly after the test."[62] Intuitive also noted that there were no FDA performance standards for these devices, but the EndoWrists were "designed, manufactured, and tested in accordance with voluntary safety standards."[63]

88. On December 12, 2001, the FDA sent a deficiency letter to Intuitive regarding the K013416 filing, requesting that Intuitive address the identified deficiencies related to usage limits, biocompatibility, and Ultrasonic Shears.[64] Specifically, the FDA wrote, "On page 12, you state that the instruments are re-usable for a limited number of uses. The instruments are programmed for a limited number of uses to ensure reliability and consistent performance, and have non volatile 'add-only' memory that the system decrements after each use. Please specify the number of uses for each instrument and describe how the numbers were determined. Please provide data to support the claim."[65]

89. Intuitive explained to FDA that the "number of uses is determined by testing instruments under conditions that replicate actual clinical use, and cycling these

[61] Ibid. at -5519.

[62] Ibid. at -5521.

[63] Ibid. at -5527.

[64] Intuitive-00481165.

[65] Ibid. at -1166.

instruments for wear expected during the specified number of procedures. . . . Performance measurements are made periodically (e.g., at the end of each cycle or set of cycles) to confirm that the instrument is still performing as intended, and the life testing is continued until failure or a specified number of cycles are successfully completed."[66]

90. On January 10, 2002, FDA granted clearance for the K013416 510(k).[67]

c) K131861

91. On June 19, 2013, Intuitive submitted a 510(k) for its Model IS4000 Da Vinci Xi surgical system and EndoWrist instruments (K131861).

92. As with the earlier submissions, Intuitive submitted performance testing data, including life testing data, demonstrating that the EndoWrist instruments had been validated for a certain number of uses.[68]

93. On March 28, 2014, FDA granted clearance for the K131861 510(k) submission.[69]

d) K170644

94. This 510(k) applies to multiple instruments and accessories that have been cleared through a number of 510(k) Premarket Notifications, including the 8mm Si Monopolar Curved Scissors. It concerns the Reprocessing Instructions provided to users for reprocessing of instruments and accessories intended for multiple usage.

[66] Ibid. at -1168.

[67] Intuitive-00481176.

[68] Intuitive-00493612.

[69] Intuitive-00861667.

95. This device was also listed as a predicate device for the K210478 510(k), discussed below in Section IV.B.1(h), in which Iconocare sought clearance for an additional 10 uses beyond what was originally cleared by FDA for the 8mm Si Monopolar Curved Scissors.

96. This submission validated the devices for the labeled number of reprocessing cycles for the instruments establishing that the device meets performance specifications after a representative number of uses.

e) K180033

97. This 510(k) was submitted by Intuitive Surgical for the EndoWrist 8mm Monopolar Curved Scissors instrument used with the Intuitive Surgical IS2000 da Vinci S Surgical System or IS3000 da Vinci Si Surgical System for cutting, cauterizing, coagulation, manipulating and blunt dissection of tissue.

98. This device was listed as one of the predicate devices for K210478. Specifically, Iconocare submitted the K210478 510(k) to seek clearance for an additional 10 uses beyond what was cleared in this 510(k) for the Si 8mm Monopolar Curved Scissors.

f) K214095

99. In December 2021, Intuitive submitted a 510(k) to FDA for "extended lives" on certain instruments intended for use with the X and Xi da Vinci Surgical Systems.[70]

[70] Intuitive-02054168.

100. The submission included testing data demonstrating that the X/Xi EndoWrist instruments could be used for a greater number of lives than the number for which they were originally cleared.[71]

101. On August 15, 2022 FDA notified Intuitive that clearance was granted for K214095.[72]

g) K143619

102. I am aware of two manufacturers other than Intuitive who have submitted 510(k)s seeking clearance to extend the usage limits on EndoWrist instruments: Rebotix, LLC and Iconocare Health.

103. Rebotix submitted K143619 on December 18, 2014 for "re-manufactured EndoWrists."[73] According to Rebotix:

> Re-manufactured EndoWrists are intended to be used in the same manner as their OEM counterparts. The conditions of use and operating principle are identical. The re-manufactured EndoWrists described above can only be used with the da Vinci S and da Vinci Si Systems, in accordance with the indication of these host systems.
>
> Specifications and allowable tolerances have been established for each of the remanufactured EndoWrists, in order to ensure that they maintain OEM-equivalent safety and performance throughout the intended extended use cycles.[74]

[71] K214095 510(k) Summary, available at: https://www.accessdata.fda.gov/cdrh_docs/pdf21/K214095.pdf. This 510(k) is discussed in further detail in Section IV.D.3.

[72] Ibid.

[73] REBOTIX170421, at -0424.

[74] REBOTIX131433 at -1436.

104. Following review of the submission and months of communications with Rebotix regarding the submission,[75] FDA issued a deficiency letter to Rebotix on June 23, 2015 that identified 51 deficiencies with the submission.[76] The deficiencies related to the device description, remanufacturing, labeling, cleaning validation, sterilization validation, biocompatibility, electromagnetic compatibility and electrical safety, and performance testing.[77]

105. It is worth noting that Phillips suggests that FDA's review of a 510(k) is not an affirmation that the subject of the 510(k) submission is "necessary."[78] However, in my experience, FDA does not devote the necessary resources to identify and describe deficiencies at this level of detail where FDA considers the 510(k) "unnecessary."

106. The term "remanufacture" (or a version of it) was used 84 times in the deficiency letter. The letter includes a specific section of deficiencies under the heading "Remanufacturing." It states:

> Remanufacturing
>
> The following deficiencies refer to the procedures you have identified to collect used devices from users, and modify those devices to accommodate additional uses (defined as "remanufacturing" for the purpose of this letter).
>
> 2. Although the subject device is not a "single-use device" (defined as a device used only once and then discarded), it has

[75] See, e.g., REBOTIX131417; REBOTIX077440; REBOTIX077545; REBOTIX077617; REBOTIX077671.

[76] REBOTIX171030.

[77] Ibid. at -1030-57.

[78] Phillips Report, ¶ 37.

> many aspects in common with third party reprocessed single-use devices. Therefore, it is recommended that you review and provide the following items described in FDA's Guidance "Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices"[79] . . .

107. It is clear from the content of the 510(k) and from FDA's deficiency letter that both Rebotix and FDA considered the activities described in this submission, which would extend the use of the EndoWrist devices for an additional 11 uses over the original clearance, to be remanufacturing.

108. FDA never cleared Rebotix's "re-manufactured EndoWrists." In the deficiency letter, FDA made clear: "You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act."[80] Again, the Phillips report tries to downplay this language by describing it as "boilerplate." In my opinion, whether it is "boilerplate" or not, FDA expects a company intending to market a new device to abide by the regulatory requirements, and would not tell a company that marketing a device would be a violation of the FD&C Act if FDA did not believe that to be the case.[81]

[79] REBOTIX171030; The guidance FDA recommended is available at https://www.fda.gov/media/71482/download (last accessed Jan. 17, 2023).

[80] REBOTIX171058.

[81] FDA may apply enforcement discretion in cases where a company made a good faith determination that a 510(k) was not needed and is actively working towards bring a product into compliance. The language in the letter indicates to me that FDA was not applying enforcement discretion here.

109. Rebotix attempted to cure the deficiencies in its submission and engaged with FDA on various calls and e-mails to gain clarity on the required activities Rebotix would need to undertake.[82] FDA explained to Rebotix that certain deficiencies stemmed "from the fact that the device is not simply a reusable device, but is a third party reprocessed/remanufactured device."[83]

110. Ultimately, Rebotix notified FDA of its intent to "formally withdraw the K143619 submission" and withdrew the submission on December 17, 2015, citing "the nature of the testing and information requested."[84] Rebotix indicated that it intended to resubmit the 510(k) at a later date, but I have seen no evidence that they did.

h) K210478

111. K210478 is the other non-OEM 510(k) submission I am aware of that seeks to extend the useful life of EndoWrist instruments.

112. It too illustrates the applicable regulatory requirements. This 510(k) was submitted by Iconocare Health in February 2021, specifically seeking clearance to add 10 uses to another manufacturer's legally marketed device.

(1) Background

113. This 510(k) is for the 8mm Monopolar Curved Scissors Instrument used with the Intuitive Surgical IS3000 da Vinci Si Surgical System for cutting, cauterizing, coagulation, manipulating and blunt dissection of tissue. The instrument consists of the

[82] REBOTIX077729; REBOTIX077735.

[83] REBOTIX077729, at -7733.

[84] REBOTIX171076.

housing, shaft, wrist, and tip. The shaft and wrist allow for different axes of rotation, and the instrument tip is used to interact with the patient tissue. This instrument is reusable and is provided non-sterile. [85]

114. The 8mm Monopolar Curved Scissor Instruments are designed by Intuitive to provide surgeons with natural dexterity and a greater range of motion than even the human hand. This allows for greater precision when operating in a minimally invasive environment. EndoWrist 8mm Monopolar Curved Scissor Instruments, when used with the IS3000 system, are designed to support rapid and precise suturing, dissection and tissue manipulation in surgical procedures.[86]

115. In the Summary of Technological Characteristics section, which is drafted by submitter, Iconocare explained that the design, materials, and intended use of the 8mm Monopolar Curved Scissor Instruments, after an additional ten (10) reuse cycles, are equivalent to the predicate device. It submitted to FDA that the mechanism of action of the subject device is identical to the predicate device in that the same standard mechanical design, materials, and sizes are utilized. Finally, Iconocare explained that the change in device specifications is to extend the useful life of the 8mm Monopolar Curved Scissor Instruments.[87]

116. In accordance with the FD&C Act and the related FDA regulations, Iconocare submitted performance data as part of its 510(k).[88] Iconocare represented to FDA

[85] SIS357813, at -7817.

[86] Ibid.

[87] Ibid.

[88] In accordance with 21 CFR 807.92(b), the 510(k) Summary for K210478 discusses the performance data submitted to support substantial equivalence. https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210478.pdf

that it conducted a risk analysis to evaluate the impact of modifications to the predicate device. This included the following tests:

- Biocompatibility
- Validation of Reprocessing
- Functional Performance Testing
- Electrical Safety Testing.[89]

117. Iconocare had to submit data sufficient to allow FDA to determine whether its remanufactured device is as safe and effective as the predicate and operates as originally intended.

(2) Deficiencies

118. [redacted].[90]

119. [redacted]:

[redacted].[92]

[89] Ibid.

[90] AHP000527.

[91] Ibid. at -0528-36.

[92] Ibid. at -0528.

120. As I explained above in Section IV.B.1(g), in my experience, especially under the current user fee performance goal structure,[93] FDA does not devote the resources required to identify and describe deficiencies at this level of significant detail when FDA considers the 510(k) "unnecessary."

121. [redacted]."[94]

122. [redacted]."[96]

123. [redacted]

[93] The performance goal system establishes a target for FDA to reach a final decision on 95% of 510(k) submissions within 90 FDA days.

[94] AHP000527, at -0528.

[95] Ibid.

[96] Ibid.

[redacted][97]

124. [redacted]

[redacted].[99]

125. [redacted]

[redacted]."[101]

[97] Ibid. at -0534.

[98] Ibid. at -0528.

[99] Available at: https://www.fda.gov/media/80265/download

[100] AHP000527 at -0531.

[101] Ibid.

126. [redacted].”[102]

127. [redacted]”[103]

128. [redacted].[105]

[102] Ibid.

[103] Ibid. at -0534. (emphasis added)

[104] Available at https://www.fda.gov/media/71482/download (last accessed Jan. 17, 2023).

[105] AHP000527, at -0534.

129. [redacted]

[redacted]."

130. Labeling[106] is defined as all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. Additionally, label is defined in Section 201(k) of the FDCA as a display of written, printed, or graphic matter upon the immediate container of any article. [107] General labeling requirements for medical devices have been established in 21 CFR Part 801.

131. [redacted]

[redacted]."[109]

[106] 21 U.S.C. §321(m).

[107] 21 U.S.C. §321(k).

[108] AHP000527, at -0536.

[109] FDA, UDI Basics, https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/udi-basics (last accessed Jan. 17, 2023); FDA, "Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended – Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices" (May 1, 2006), available at https://www.fda.gov/media/71187/download (last accessed Jan. 17, 2023).

132. [redacted].[110]

133. [redacted]."[111]

134. [redacted].[112]

135. [redacted]."[113]

[110] 21 CFR § 801.20(a).

[111] Restore-00086093, at -6100.

[112] Ibid. at -6096-6100.

[113] Ibid. at -6107–08. This appears to contradict Kevin May's recent representation that as long as a hospital "continues to own" an EndoWrist instrument, it can send it to Restore, who

(3) Clearance

136. [redacted]."[115]

137. Upon clearing the device, FDA assigned this instrument the product codes NAY and QSM. See **Figure 1**.

expects to be purchasing the K210478 clearance from Iconocare and remanufacturing EndoWrists according to Iconocare's cleared process, to have the usage limits reset as many times as "we're willing to reset it." May Tr. 17:21-18:25; 137:23-140:4.

[114] K210478 510(k) Summary, available at: https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210478.pdf (last accessed Jan. 17, 2023).

[115] Restore-00086093 (emphasis added).

Figure 1

Device Classification Name	system, surgical, computer controlled instrument, remanufactured
510(k) Number	K210478
Device Name	8mm Monopolar Curved Scissors
Applicant	Iconocare Health 7825 East Redfield Rd. Suite 103 Scottsdale, AZ 85260
Applicant Contact	Rick Ferreira
Correspondent	Iconocare Health 7825 East Redfield Rd. Suite 103 Scottsdale, AZ 85260
Correspondent Contact	Rick Ferreira
Regulation Number	876.1500
Classification Product Code	QSM
Subsequent Product Code	NAY
Date Received	02/19/2021
Decision Date	09/30/2022
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Gastroenterology/Urology
510k Review Panel	General & Plastic Surgery
Statement	Statement
Type	Traditional
Reviewed by Third Party	No
Combination Product	No

138. As discussed further in Section IV.B.3(a), the NAY product code refers to a "System, Surgical, Computer Controlled Instrument."[116] The QSM code, which was created as a result of this initial clearance for a device cleared as a remanufactured NAY instrument—refers to a "System, Surgical, Computer Controlled Instrument, ***Remanufactured***."[117] The physical state of a device with the QSM code is described by FDA:

> A surgical instrument for a computer controlled system. The instrument has been ***remanufactured to extend its use life*** as

[116] Product Classification, NAY, available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=NAY (last accessed Jan. 17, 2023).

[117] Product Classification, QSM, available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=5726 (last accessed Jan. 17, 2023) (emphasis added).

compared to what was originally defined by the original equipment manufacturer."[118]

2. FDA has acknowledged the limited use nature of EndoWrist instruments in communications to third parties.

139. [redacted]."[119]

140. FDA acknowledged in its 2015 deficiency letter to Rebotix that the EndoWrists could only be validated for a certain number of lives ("[P]lease provide all details regarding the device description, remanufacturing process, validated reprocessing instructions for users, and validated number of use lives . . .").

141. [redacted].[121]

[118] Ibid. (emphasis added)

[119] Restore-00001248, at -1256; REBOTIX146948, at -6954-55.

[120] REBOTIX171030.

[121] AHP000527, at -0534.

142. [redacted].[124]

3. Objective and publicly available evidence demonstrates that FDA has determined that removing or extending the usage limitation on EndoWrist instruments is a remanufacturing activity, and as such, it requires 510(k) clearance.

a) FDA has classified remanufactured EndoWrists as Class II devices, assigned them a unique procode, and indicated that they require 510(k) clearance.

143. FDA's classification of EndoWrist instruments as Class II devices and the assignment of two product codes for the devices demonstrates that FDA views extending the usage limitation on EndoWrist instruments as a remanufacturing activity requiring 510(k) clearance.

144. FDA considers EndoWrist instruments to be robotically-assisted surgical (RAS) devices.

145. RAS devices are a type of computer-assisted surgical system. Sometimes referred to as robotic surgery, RAS devices enable the surgeon to use computer and software

[122] Ibid. at -0528; REBOTIX171030, at -1034.

[123] "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (June 9, 2017), at 20.

[124] Intuitive-00705778, at -5779.

technology to control and move surgical instruments through one or more tiny incisions in the patient's body (minimally invasive) for a variety of surgical procedures.[125]

146. In FDA's view, the benefits of a RAS device may include its ability to facilitate minimally invasive surgery and assist with complex tasks in confined areas of the body. The device itself is not actually a robot because it cannot perform surgery without direct human control.[126]

147. RAS devices generally have several components, which may include a:

- Console: Where the surgeon sits during surgery. The console is the control center of the device and allows the surgeon to view the surgical field through a three-dimensional endoscope and control movement of the surgical instruments;
- Bedside cart: Includes three or four hinged mechanical arms, camera (endoscope) and surgical instruments that the surgeon controls during surgical procedures;
- Separate cart: Contains supporting hardware and software components, such as an electrosurgical unit (ESU), suction/irrigation pumps, and light source for the endoscope.[127]

148. FDA classifies RAS devices as Class II devices. Manual surgical instruments for general use (non-powered, hand-held devices) are Class I, exempt from 510(k) under 21 CFR 878.4800. In comparison, because of the risk profile, RAS devices are classified by FDA as Class 2

[125] FDA, Computer-Assisted Surgical Systems, https://www.fda.gov/medical-devices/surgery-devices/computer-assisted-surgical-systems (last accessed Jan. 17, 2023).

[126] Ibid.

[127] Ibid.

and require a 510(k) before the device may be marketed.[128] Specifically, FDA has determined that RAS devices require both general and special controls in order to provide a reasonable assurance of safety effectiveness, while traditional surgical tools require only general controls.

149. FDA has created two product codes under the regulation 21 CFR § 876.1500 for the instruments that are used with robotically-assisted surgical systems.[129]

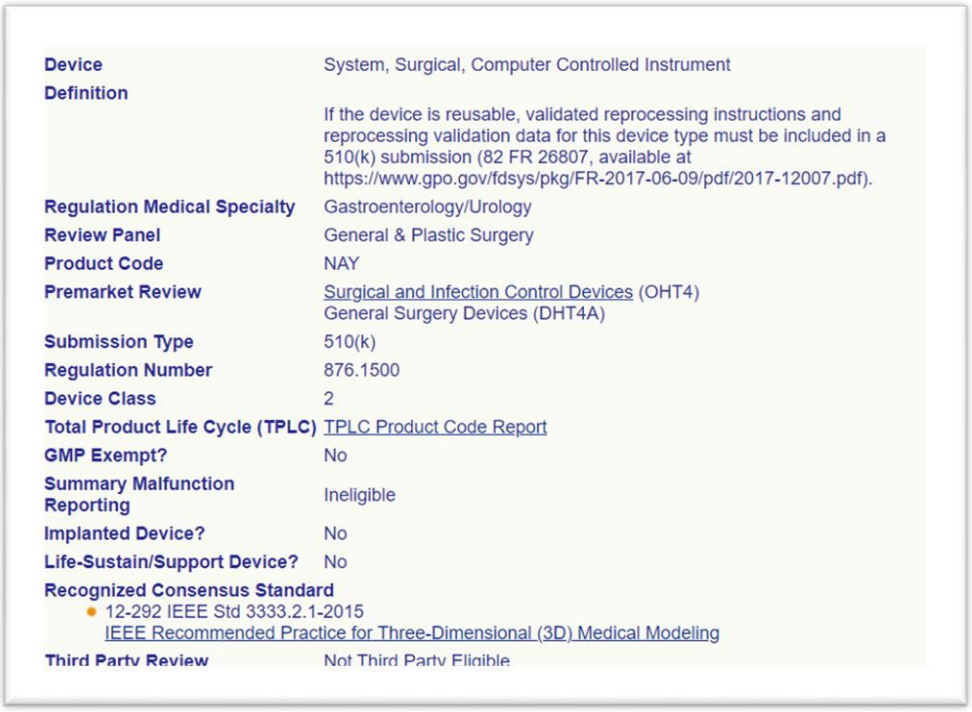
150. One product code (NAY) is for what FDA would consider original equipment. See **Figure 2**. NAY refers to "System, Surgical, Computer Controlled Instrument," and devices with this product code are Class 2. Such a device requires 510(k) clearance to be legally marketed. The product code includes the following statement:

> *If the device is reusable, validated reprocessing instructions and reprocessing validation data for this device type must be included in a 510(k) submission.*

[128] FDA's classification of traditional and robotic surgical devices in different classes pertains to FDA's assessment of the risk profile and the controls necessary to provide reasonable assurance of safety and effectiveness.

[129] A summary of relevant premarket submissions with the NAY and QSM product codes that have been reviewed and cleared by FDA are summarized in Appendix C.

Figure 2



Device	System, Surgical, Computer Controlled Instrument
Definition	If the device is reusable, validated reprocessing instructions and reprocessing validation data for this device type must be included in a 510(k) submission (82 FR 26807, available at https://www.gpo.gov/fdsys/pkg/FR-2017-06-09/pdf/2017-12007.pdf).
Regulation Medical Specialty	Gastroenterology/Urology
Review Panel	General & Plastic Surgery
Product Code	NAY
Premarket Review	Surgical and Infection Control Devices (OHT4) General Surgery Devices (DHT4A)
Submission Type	510(k)
Regulation Number	876.1500
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Ineligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Recognized Consensus Standard	• 12-292 IEEE Std 3333.2.1-2015 IEEE Recommended Practice for Three-Dimensional (3D) Medical Modeling
Third Party Review	Not Third Party Eligible

151. The second product code (QSM) was specifically created for remanufactured products. See **Figure 3.** QSM refers to "System, Surgical, Computer Controlled Instrument, Remanufactured," and devices with this product code are Class 2. Such a device requires 510(k) clearance to be legally marketed. The product code includes the following statement:

> *The instrument has been remanufactured to extend its use life as compared to what was originally defined by the original equipment manufacturer.*

Figure 3

Device	System, Surgical, Computer Controlled Instrument, Remanufactured
Definition	As intended with the originally cleared instrument.
Physical State	A surgical instrument for a computer controlled system. The instrument has been remanufactured to extend its use life as compared to what was originally defined by the original equipment manufacturer.
Technical Method	Instrument is attached and manipulated from a primary computer controllec system.
Target Area	Where applicable in accordance to the indications for use.
Regulation Medical Specialty	Gastroenterology/Urology
Review Panel	General & Plastic Surgery
Product Code	QSM
Premarket Review	General Surgery Devices (DHT4A) General Surgery Devices (DHT4A)
Submission Type	510(k)
Regulation Number	876.1500
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Ineligible
mplanted Device?	No
ife-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

152. As discussed in Section IV.B.1(h), FDA granted clearance to Iconocare for a remanufactured EndoWrist (8mm Monopolar Curved Scissors) and classified the instrument as: "system, surgical, computer controlled instrument, remanufactured."

153. FDA created the QSM product code as a result of the clearance of the Iconocare-remanufactured EndoWrist. The product code for the cleared Iconocare technology states: "The instrument has been remanufactured to extend its use life as compared to what was originally defined by the original equipment manufacturer."

154. From an FDA regulatory perspective, the creation of the QSM code – and classification as a Class II device – by FDA means that FDA has determined that the extension of the use life for a surgical instrument for a computer controlled system, as compared to what was originally defined by the original manufacturer, requires 510(k) clearance. FDA would not

create a new product code for an "unnecessary" 510(k); doing so requires extra administrative effort and levels of approval. This is further evidence that FDA requires 510(k) clearance to extend the use life for any EndoWrists.

b) Congress also reached the same conclusion for a similar industry and activity – reprocessing – and amended FDA's governing statute to define premarket requirements for the reprocessors of devices labeled for single use.

155. FDA's regulation of reprocessing is informative to the issues here, particularly with respect to the reprocessing of single-use devices.

156. Extending the usage limit of EndoWrists beyond their intended limits is an activity very similar to SUD reprocessing. SUD reprocessors facilitate the reuse of instruments labeled for a single use to extend their "life" for additional uses.

157. Even FDA has identified EndoWrists as having similar characteristics to single-use devices and indicated that certain reprocessing guidance documents are relevant to the premarket notification requirements for a "reset" EndoWrist instrument.[130]

158. "Reprocessing" refers to cleaning and sterilization of medical devices — for example, cleaning and sterilizing reusable medical devices between uses, consistent with the FDA cleared or approved instructions for use for the device, and cleaning or sterilizing devices originally labeled for single use only, i.e. single-use devices ("SUDs").

159. Congress has addressed reprocessing with respect to single-use devices. Reprocessing a single-use device refers to reprocessing a device that is labeled by the OEM for single use for an additional use.

[130] REBOTIX155894 (Deficiency #2).

160. In 2002, Congress passed the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) to address reprocessing of SUDs.[131] The MDUFMA legislation amended the FD&C Act, establishing new statutory requirements applicable to reprocessed SUDs, including labeling identifying the devices as reprocessed,[132] submission of validation data in premarket notifications (510(k)s), as well as a submission like a PMA for Class III SUDs known as Premarket Report (PMR).[133]

161. FDA defined the policy that firms and hospitals that are reprocessing SUDs are considered by FDA to be manufacturers and as such must comply with all of the following statutory and regulatory requirements, where applicable:[134]

- Quality System Regulation (Section 520(f) of the Act; 21 CFR Part 820)
- Medical Device Reporting (Section 519 (a), (b) and (c) of the Act; 21 CFR Part 803)
- Registration and Listing (Section 510 of the Act; 21 CFR Part 807)
- Labeling (Section 502 of the Act; 21 CFR Part 801)
- Premarket Approval (including Premarket Reports for reprocessed single-use devices) Section 515 of the Act; 21 CFR Part 814)
- Premarket Notification (510(k)) (Sections 510, 513 ; 21 CFR Part 807)
- Medical Device Corrections and Removals (Section 519(f) of the Act; 21 CFR Part 806)

[131] Medical Device User Fee and Modernization Act of 2002, PL 107–250, October 26, 2002, 116 Stat 1588; 21 U.S.C. § 360(o).

[132] 21 U.S.C. § 352(u)(2).

[133] 21 U.S.C. § 360(o); FDA, Summary of the Medical Device User Fee and Modernization Act of 2002, https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/summary-medical-device-user-fee-and-modernization-act-2002 (last accessed Jan. 18, 2023).

[134] CPG § 300.500 (Reprocessing of Single Use Devices), available at: https://www.fda.gov/media/71769/download (last accessed Jan. 17, 2023).

- Medical Device Tracking (Section 519(e) of the Act; 21 CFR Part 821).

162. Because FDA considers reprocessors of SUDs to be manufacturers, those reprocessors are subject to premarket and postmarket requirements, such as 510(k) notification. The applicability of the 510(k) requirement to reprocessed single-use devices is codified at 21 U.S.C. § 360(o), which specifies the type of data that must be included in the 510(k) for reprocessed devices:

> (1) With respect to reprocessed single-use devices for which reports are required under subsection (k):
>
> (A) The Secretary shall identify such devices or types of devices for which reports under such subsection must, in order to ensure that the device is substantially equivalent to a predicate device, include validation data, the types of which shall be specified by the Secretary, regarding cleaning and sterilization, and functional performance demonstrating that the single-use device will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification.

163. It should be noted that Congress did not *need* to revise the governing statute in order to impose premarket requirements on the SUD reprocessors. However, Congress amended the regulation to define the requirements.

164. Here, Congress does not need to step in. As explained in Section IV.A, remanufacturing is already clearly defined in the regulations, which have the same force of law as the governing statute, and is subject to the premarket requirements.

4. Third parties engaging in extending or resetting the lives of EndoWrist instruments are remanufacturers under existing FDA regulation. Therefore, they were required to obtain 510(k) clearance.

a) The activities that the third parties undertake to extend the usage limits significantly change the performance specifications of EndoWrist instruments.

165. An essential part of the design for the EndoWrist instruments is the limitation on the number of times each instrument may be used for surgical procedures. As I understand, the limitation is implemented through an integrated circuit that tracks the number of times an instrument is used by a da Vinci robot.[135]

166. As I understand, during manufacturing, the chip is programmed with the total number of allowed uses; for most S and Si EndoWrist instruments, this usage limit is ten surgical procedures. When an instrument is connected to the robot, the chip in the instrument communicates with the robot, and a use is decremented. Once the uses have been decremented to zero, the robot will not activate the instrument.[136]

167. As explained above in Section IV.B.1(a)-(f), this information was provided to and evaluated by FDA, which cleared the EndoWrist as a limited use device.

168. As I understand, the change that third parties are making or attempting to make is to the number of uses as specified in the labeling for the devices from the OEM by modifying or replacing the OEM counter to allow uses beyond the OEM limit.

169. There are two technologies that I am aware of that have been developed in order to remove and/or extend the usage limitation on EndoWrist instruments.

[135] Expert Report of Dr. Robert D. Howe (Aug. 20, 2021) (*Restore Robotics LLC et al. v. Intuitive Surgical, Inc.*) ("Howe Report (*Restore*)") ¶ 25.

[136] Howe Report (*Restore*) ¶ 25.

170. It is my understanding that in order to bypass the usage counter on EndoWrist instruments, SIS facilitated a "reset" service involving technology from Rebotix Repair LLC ("Rebotix") called the "Interceptor." SIS has not performed the reset process itself, but instead relied entirely on Rebotix to actually perform the reset.[137] SIS intends to begin resetting instruments pursuant to the Rebotix process at some point in the future.[138]

171. It is my understanding that SIS's facilitation involved collecting from hospitals used EndoWrist instruments and sending them to Rebotix in Florida to perform the "reset" process.[139] I also understand that, for a period, Restore Robotics Repair also performed the reset on behalf of Rebotix out of a facility in Anaheim, CA.[140]

172. As I understand, Rebotix's method intercepts communication between the robot and the instrument. During the process, the device is opened by brute force, the original circuit board is removed, the OEM chip is desoldered to remove it, and then it is soldered onto the Interceptor board. The Interceptor technology allows the third party to substitute an altered number of uses to allow the instrument to exceed the original, cleared usage limit.[141]

---

[137] Expert Report of Dr. Robert D. Howe (Dec. 2, 2022) *(Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*) ("Howe Report (*SIS*)") ¶¶ 8, 34; 30(b)(6) Deposition of Greg Posdal (Nov. 1, 2022), Tr. 21:17-24, 22:10-12; 30(b)(6) Deposition of Keith Johnson (Oct. 27, 2022), Tr. 33:22-34:4.

[138] Phillips Report ¶ 94.

[139] Howe Report (*SIS*) ¶ 8.

[140] Deposition of Kevin May (Nov. 3, 2022), Tr. 105:14-22.

[141] Howe Report (*SIS*), ¶¶ 35-36.

173. This process for resetting the usage counter has never been cleared by FDA. As discussed above in Section IV.B.1(g), Rebotix sought out 510(k) clearance but later abandoned such an effort.

174. [redacted].[142]

175. As discussed above in Section IV.B.1(h), FDA reviewed this process as it is applied to Si 8mm Monopolar Curved Scissors and granted 510(k) clearance to Iconocare for remanufactured Si 8mm Monopolar Curved Scissors. FDA cleared Iconocare to only perform the reset process once on any given instrument, and this process has not been cleared by FDA to be used to reset any other instrument.

176. The third parties do not "return[the finished device] to the safety and performance specifications established by the OEM and to meet its original intended use."[143] Because their activities significantly change the device's performance specifications, their activities are considered by the FDA to be remanufacturing.

177. As discussed above, the Rebotix (and Iconocare) processes include a method that alters the performance specifications of the EndoWrists. The Rebotix

[142] Restore-00089490, at -9495, -9498; Supplemental Expert Report of Dr. Robert D. Howe (Dec. 23, 2022) (*Restore*) ("Howe Supplemental Report (*Restore*)"), ¶¶ 144-45.

[143] FDA, "White Paper: Evaluating Whether Activities are Servicing or Remanufacturing" (December 2018), at 19, available at https://www.fda.gov/media/117238/download (last accessed Jan. 17, 2023); 21 CFR 820.3(w) (defining remanufacturer as a person who "dos any . . . act to a finished device significantly changes the finished device's performance or safety specifications, or intended use"); Phillips ¶¶ 84, 96.

"Interceptor," which replaces the original circuit board in the instrument and manipulates the data on the original chip, intercepts communication between the robot and the instrument and extends the performance of an EndoWrist beyond the original specified uses. The Iconocare process similarly changes the performance specifications through a process which replaces both the circuit board and the Dallas chip in order to bypass the originally-specified usage limits.

178. It is beyond dispute that the EndoWrist instruments sold by Intuitive are designed and manufactured to perform for the specified number of uses, which have been reviewed and cleared by FDA. By removing or extending the usage limitation, the third parties are significantly changing the performance of the instrument.

179. Such an activity constitutes remanufacturing and is therefore subject to the 510(k) premarket requirements.

b) The activities that the third parties undertake to extend the usage limits significantly change the safety specifications of EndoWrist instruments.

180. The third parties' processes also significantly change the safety specifications. The EndoWrist instruments were evaluated by Intuitive to determine the bounds of safe and reliable use and reprocessing of each instrument and assigned the usage limitations accordingly. By extending the usage limits, the third parties are changing the safety specifications beyond what was originally validated by the original equipment manufacturer.

181. FDA has explained that changes to the reprocessing of the EndoWrist devices require a 510(k) because a System, Surgical, Computer controlled Instrument (product code NAY), which is how FDA classifies EndoWrists, poses a greater likelihood of microbial transmission and represents a high risk of infection if it is not adequately reprocessed.

Extending the lives of an EndoWrist instrument necessarily involves changing the reprocessing instructions (by allowing additional reprocessing cycles beyond what was validated). "A 510(k) to change the reprocessing instructions of a cleared EndoWrist requires a new 510(K) submission for FDA to evaluate substantial equivalence."[144]

182. As such, by removing or extending the usage limitation, the third parties are significantly changing the safety specifications of the instrument.

183. Phillips seems to draw conclusions from the fact that there are no adverse events reported in the MAUDE database involving EndoWrist devices that include references to the third parties.[145] However, this has no relevance to FDA's evaluation of whether an activity "significantly changes the finished device's . . . safety specifications," and Phillips's argument is misleading.

184. First, it is important to understand FDA's adverse event reporting requirements. FDA uses Medical Device Reporting (MDR) as a postmarket surveillance tool to "monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products."[146]

185. Certain entities are mandatory reporters. For example, "device user facilities" are required to report a suspected medical device-related death to both the FDA and

[144] Intuitive-00705778, at -5779.

[145] Phillips Report ¶ 112.

[146] FDA, Medical Device Reporting (MDR): How to Report Medical Device Problems, https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems (last accessed Jan. 17, 2023).

the manufacturer and serious injuries to the manufacturer.[147] A device user facility is a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility, which is not a physician's office.[148]

186. Manufacturers are also "mandatory reporters." They are required to submit to FDA certain types of reports for adverse events and malfunctions associated with medical devices. Specifically, manufacturers are required to report to FDA when they learn that any of their devices "may have caused or contributed to a death or serious injury" and when they become aware that their device has malfunctioned and "would be likely to cause or contribute to a death or serious injury if the malfunction were to recur."[149]

187. Because remanufacturers are considered by FDA to be manufacturers, they are fully responsible for compliance with all FDA requirements for manufacturers, including submitting MDRs to inform FDA of adverse events and malfunctions with the potential to cause harm associated with their remanufactured devices.[150]

188. FDA records mandatory reports filed by manufacturers and importers from August 1996 to present on the Manufacturer and User Facility Device Experience (MAUDE) database. The MAUDE database houses MDRs submitted to the FDA by mandatory

[147] 21 CFR § 803.10(a).

[148] 21 CFR § 803.3(d).

[149] 21 CFR § 803.10(c); 21 CFR § 803.3(o); 21 CFR § 803.50.

[150] 21 CFR § 803.50.

reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.[151]

189. If a manufacturer does not comply with its duty to report or believes it has no duty to report, then no reports would appear in the MAUDE database.

190. Similarly, if an entity is remanufacturing the original manufacturer's devices without complying with FDA's requirements for manufacturers, including registration, premarket notification, and reporting, then any adverse events associated with the remanufactured instrument would only appear as associated with the original manufacturer.

191. Even where a remanufacturer has complied with FDA's regulatory requirements, users, including hospitals, may continue to report reportable events to the original manufacturer.

192. Second, the absence of reported safety issues associated with a device does not affect the FDA's determination of whether an activity being performed on the device significantly affects the safety *specifications* of the device.

193. As discussed above in Section III.C.1, FDA's focus is on whether the activity in question *could* significantly affect the safety or effectiveness of the device. The absence of adverse events doesn't necessarily have a direct bearing on this assessment in my experience. But the presence of adverse events could have an impact.

c) The third parties are introducing new devices into interstate commerce, which makes their activity subject to FDA requirements.

[151] FDA, Medical Device Reporting (MDR): How to Report Medical Device Problems, https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems (last accessed Jan. 17, 2023).

194. It is worth also noting that FDA regulatory requirements apply where the product has been introduced into interstate commerce. In my experience preparing cases for FDA, interstate commerce could be established by the transport of a finished device across state boundaries or it could be established by the transport of components or products across state boundaries that are then used in the finished device.

195. Section 201(b) of the FD&C Act [21 U.S.C. 321(b)] tells what circumstances place a product in interstate commerce:

> "(1) commerce between any State or Territory and any place outside thereof, and
>
> (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body."

196. According to the FDA website:[152]

> "Interstate commerce" applies to all steps in a product's manufacture, packaging, and distribution. It is very rare that a cosmetic product on the market is not in "interstate commerce" under the law. For example, at least some of your ingredients or packaging most likely originate from out of state, or even out of the country. Likewise, it is foreseeable that your products will leave the state.

197. While the above paragraph speaks to cosmetic products, FDA uses the same definition for interstate commerce for all of its regulated products (drugs, devices, biologics, foods, etc.).

[152] FDA, Key Legal Concepts for Cosmetics Industry: Interstate Commerce, Adulterated, and Misbranded, https://www.fda.gov/cosmetics/cosmetics-laws-regulations/key-legal-concepts-cosmetics-industry-interstate-commerce-adulterated-and-misbranded (last accessed Jan. 17, 2023); 21 U.S.C. § 321(b).

198. Utilizing these principles, the activities conducted would meet FDA's definition of interstate commerce in my experience and opinion.

199. There is evidence that SIS, Rebotix, and Restore have all introduced these remanufactured devices into interstate commerce. The third parties have shipped or facilitated the shipping of remanufactured EndoWrists to hospitals in Texas, New York, Massachusetts, Arkansas, and other states from their locations in California and Florida.[153]

d) The third parties' arguments that they are not remanufacturers are incorrect.

200. What the third parties do is in fact remanufacturing. There is no ambiguity on this point, and Intuitive was correct in its belief that the third parties' activities violated FDA regulations. Moreover, SIS's decision to engage in these activities without 510(k) clearance was unreasonable.

201. As explained above, a remanufacturer is a person who engages in acts "to a finished device that significantly changes the finished device's performance or safety specifications, or intended use." And as demonstrated in Sections IV.A.B.4(a) and (b),the activities at issue here significantly change the device's performance and safety specifications.

202. FDA's Center for Devices and Radiological Health (CDRH) is "responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States." CDRH's focus is on the underlying activity, not who the firm is.

203. Whether an entity self-describes as a "repair" company does not change the nature of their activities.

[153] REBOTIX175326; Restore-00055935; Restore-00055937.

204. Similarly, whether or not a "repair" company takes title of the instrument or sells the instrument to a different hospital is not relevant to a determination that the activity is remanufacturing. Under FDA's existing regulations, ownership of a medical device does not impact a regulatory determination. That determination is driven by the particular activity being performed on the device.

205. [redacted].

206. Any entity that engages in the activities described in FDA's definition of remanufacturing is a remanufacturer, regardless of title, ownership, or whether that entity identifies as a repairer or servicer.

[154] Phillips Report ¶ 82. Restore's Kevin May testified that the "repair" and "remanufacturing" processes expected to be employed by Iconocare are the same activity. He testified that the difference between the two is that Iconocare will comply with FDA's labeling requirements when Iconocare sells the instruments but will not comply if Iconocare does not take ownership of the device. May Tr. 80:8-14; 102:4-7. Moreover, he testified that Iconocare could use the process to reset *any* instrument any number of times for the same reasons. May Tr. 137:23-140:4. This is in direct violation of FDA's regulations and FDA's own directive to Restore. K210478 510(k) Summary ("Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices . . .").

207. In 1998, FDA revoked Compliance Policy Guide (CPG) 7124.28, Reconditioners/Rebuilders of Medical Devices,[155] "because application of [then-]current good manufacturing practice (CGMP) requirements to 'reconditioners/rebuilders' of used medical devices [did] not comport with definitions in the quality system (QS) regulation or guidance in the final rule that applies CGMP requirements to 'manufactures' and 'remanufacturers.'"[156]

208. Before the revocation, CPG 7124.28 interpreted Section 510 of the Act and defined a "reconditioner/rebuilder"' as a "person or firm that acquires ownership of a used device and, for purposes of resale or commercial distribution, ''restores'' or ''refurbishes'' the device to the manufacturer's original or current specifications, or new specifications."[157]

209. However, after the new term "remanufacturer" was added to 21 CFR 820 and defined, as above, in 21 CFR 820.3(w), FDA determined that the guidance in CPG 7124.28 had become obsolete because its terminology and application of CGMP requirements no longer conformed with the terms and applicability of the regulations.[158]

210. FDA explained: "FDA no longer believes that the processing, remarketing, or servicing of used devices should be characterized in terms of whether or not the processor acquires ownership of the device for purposes of resale or remarketing."[159] FDA indicated that this decision was made "on the basis of industry concerns raised during CGMP rulemaking,

[155] CPG 7124.28 was issued on December 29, 1987 and revised in March 1995.

[156] 63 Fed. Reg. 67076 (Dec. 4, 1998).

[157] Ibid.

[158] Ibid. at 67077.

[159] Ibid.

FDA's knowledge of changes in the used-device market, and information on used-device 'remarketers' and 'servicers' obtained through the International Association of Medical Equipment Remarketers."[160]

211. FDA explained that the more important distinction was "between the types of processing conducted on used devices ***on the basis of whether or not significant changes occur, or are made, in the performance or safety specifications or intended use of the finished device, as a result of the processing.***"[161]

212. Notably, FDA's revocation of this distinction came after advocacy from SUD reprocessors, who argued that reprocessors "differ significantly" from refurbishers, "as is" remarketers, services, and reconditioners/rebuilders in part *because* "the hospital retains ownership," and reprocessors never "acquire ownership of medical devices" or "resell or commercially distribute devices."[162]

213. Despite this advocacy, FDA rejected this argument, deciding that its focus was on "used-device processors making significant modifications to finished devices," regardless of whether the entity held title or acquired ownership to the device.[163]

214. FDA has not revoked or changed this guidance.

215. Phillips points out that FDA anticipated issuance of a rule or further guidance setting forth the agency's current position on the applicability of regulatory

[160] Ibid.

[161] Ibid. (emphasis added)

[162] See, e.g., Letter from Counsel to the Association of Medical Device Reprocessors to FDA (Mar. 23, 1998)

[163] 63 Fed. Reg. 67076 at 67077.

requirements to "reconditioners/rebuilders" of used devices[164] but "has not promulgated a regulation pertaining to the 'used device market' and no guidance document outlining the Agency's thinking on the matter is in effect."[165] However, the lack of a final rule or further guidance on "reconditioners/rebuilders" is irrelevant to FDA's conclusion that entities whose activities significantly change the performance or safety specifications, or intended use of a finished device are remanufacturers (and therefore manufacturers), subject to applicable regulatory requirements, including premarket notification, regardless of whether they take ownership of the subject device.

216. Because the third parties were remanufacturing EndoWrist instruments, a 510(k) clearance was required, and SIS's decision to not pursue 510(k) clearance for these activities had no basis in a reasonable interpretation of the law.

C. Opinion 3 – FDA communicated to certain third parties that their activities constituted remanufacturing.

217. FDA has told Iconocare, Restore, and Rebotix that resetting or extending the usage limits beyond their cleared limit constitutes remanufacturing.

218. First, as explained in Section IV.B.1(g), Rebotix applied for 510(k) clearance in 2014 and later withdrew that application after receiving a 51-item deficiency letter from FDA, indicating that FDA required additional information and data from Rebotix before it could determine that Rebotix's "re-manufactured" EndoWrists could be safely used. Rebotix

[164] Ibid. at 67078.

[165] Phillips Report ¶ 59.

cited the nature of the testing and information requested" by FDA as the reason for its decision to withdraw the submission.[166]

219. In the June 2015 deficiency notification to Rebotix, FDA stated clearly that the remanufactured EndoWrists could not be marketed until Rebotix had received a letter allowing it to do so: "If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act."[167]

220. Phillips suggests that this boilerplate language "means nothing" when a 510(k) is "unnecessary." As I explained above in Section IV.B.1(g), FDA does not make a practice of investing the time and resources required to identify 51 deficiencies in a 510(k) submission it considers "unnecessary." And more importantly, whether or not the language in the deficiency that Rebotix may not market the remanufactured EndoWrists without a 510(k) is "boilerplate" does not diminish its weight as a determination by FDA. FDA expects that its determinations will be complied with and would not include such language if it did not.

221. Second, on May 21, 2018, Bob Overmars, President and CEO at BPI Medical, e-mailed Dr. Cal F. Rabang, a biomedical engineer who works at FDA in [CDRH/ODE/DSD/GSDB2] inquiring (on behalf of Rebotix) why FDA was "concerned" about the so-called repair companies having a 510(k), arguing that BPI "repair[s] 1000's of reusable Endoscopic Instruments and the FDA does not require a 510K to repair those."[168] Dr. Rabang responded on June 6, 2018:

[166] REBOTIX171076.

[167] REBOTIX171058.

[168] BPI000331, at BPI000336.

> § Specifically for the reusable Endowrist Instruments, if the use-life counter is reset or extended past the number of available use lives, then the device specifications are changed. As such, you would be considered a remanufacturer per 21 CFR 820.3(w). In addition, if during the repair process the device is cleaned, disinfected and/or sterilized, then you would be considered a 3rd party reprocessor.
>
> § Remanufacturers and 3rd Party Processors meet the definition of "manufacturer" specified in 21 CFR 820.3(o) and are required to register and list according to 21 CFR 807.20. In addition, Endowrist Instruments are classified as Class II devices per 21 CFR 876.1500, Product Code NAY. As such, you would be subject to premarket notification (510(k)) requirements defined in 21 CFR 807.81.
>
> I hope this provides enough explanation regarding the 510(k) requirements for repair of da Vinci reusable Endoscopic Instruments.[169]

222. Overmars forwarded this e-mail to Glenn Papit at Rebotix, who forwarded the same to Chris Gibson and Stan Hamilton, who I understand to have been employees at Rebotix.[170] In response, Hamilton explained that there was "no need to respond" to FDA because it would be "revisiting the path that Rebotix went down in some agonizing detail over 2 years ago."[171]

223. [redacted]

[redacted]

[redacted]

[169] Ibid. at BPI000335.

[170] Ibid. at BPI000334.

[171] Ibid. at BPI000333.

[redacted]

[redacted]."[172]

224. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]:

[172] REBOTIX146948, at -6955; Restore-00001248, at -1256.

[173] Restore-00001248, at -1254 (emphasis added)

[174] Ibid (emphasis added).

225. Rebotix made the same argument to FDA and received the same response and list of questions.[175] FDA clearly communicated its position to both Restore and Rebotix that FDA was concerned that the underlying activity constituted remanufacturing without clearance, regardless of the ownership of the device.

226. FDA told Rebotix in November 2021 again that its activities constituted remanufacturing. On November 16, 2021, Intuitive sent a "It Has Come To Our Attention" letter, explaining that FDA received information that Rebotix "may be remanufacturing the da Vinci S EndoWrist Instruments."[176]

227. In certain situations, CDRH may become aware that regulated industry may be promoting a medical device in a manner that potentially violates the Federal Food, Drug, and Cosmetic Act and its implementing regulations. CDRH may issue an "It Has Come to Our Attention" Letter (IHCTOA Letter) to regulated industry as an early communication to gather additional information. An ICHTOA Letter can be a precursor to an enforcement action if FDA does not obtain a response that alleviates FDA's concerns.[177]

228. In this letter, FDA explained that it conducted a review of its file and had "been unable to identify any Food and Drug Administration (FDA) clearance approval number

[175] REBOTIX146948, at -6952-6954. Rebotix responded to FDA's e-mail with responses on March 19, 2020. Ibid. at -6948-6952. Restore never provided any responses to FDA's questions but instead represented that it had ceased all activity on EndoWrist instruments. Restore-00001248, at -1249.

[176] REBOTIX175417.

[177] FDA, Letters to Industry, https://www.fda.gov/medical-devices/industry-medical-devices/letters-industry (last accessed Jan. 17, 2023).

for the da Vinci S EndoWrist Instruments to support the services described on your website . . . and described in a prior email communication to the Agency dated March 19, 2020."[178]

229. FDA continued: "Specifically, the da Vinci S EndoWrist Instruments were cleared for a set number of uses. By extending the number of uses, your activities may be altering the intended use of the subject device."[179]

230. Rebotix responded to FDA's letter on January 13, 2022, reiterating its argument that it does not take ownership of the devices and therefore cannot be a remanufacturer, and that it had not sought FDA clearance or approval "because it is not required to do so."[180]

231. On April 6, 2022, Anthony Lee, a Team Lead on the Robotic-Assisted Surgery Devices Team in CDRH at FDA, informed Rebotix that a decision had been made in relation to the It Has Come To Our Attention letter. On April 8, Lee e-mailed Rebotix, writing, "As mentioned during our call, the Agency believes that the activities of Rebotix constitute remanufacturing and would require FDA review and clearance (e.g. 510(k) / de Novo). We therefore request that Rebotix stop engaging in the current activities until an application is reviewed and cleared/granted."[181]

232. Lee explained, "The instruments in question no longer maintain the same safety and effectiveness profile as cleared with the original manufacturer's own submission. During premarket review, FDA reviews test data to the labeled number of reuse cycles. . . . ***By***

[178] REBOTIX175417.

[179] Ibid.

[180] REBOTIX175468.

[181] REBOTIX175710, at -5726-28.

extending the number of uses and modifying the instrument with a new chip, the prior information is no longer valid and requires additional review to the new labeled usage limit in order to establish safety and effectiveness. **This is therefore different than returning the device to its original condition."**[182]

233. [redacted][183]

234. However, it is my opinion that the information was being communicated by the reviewer. The reviewer offers opinions. It appears from the documents that Rebotix was contemplating appealing FDA's decision, and it is my opinion that the reviewer was trying to indicate that this opinion was not subject to a supervisory appeal under 21 CFR 10.75. Moreover, the communication ended with a suggestion that, if Rebotix wanted to take this further, they should submit a 510(k). Rebotix's other option would have been a 513(g), which they did not pursue. All of this indicates that FDA had not deviated from its position that a 510(k) was needed, and Rebotix never took any formal steps to seek a final, different decision on that.

[182] Ibid. at -5727 (emphasis added)

[183] Ibid. at -5839.

235. It is my opinion that the reviewer's opinion is consistent with the review practices observed from the 510(k) reviews that did receive management sign-off as well as the creation of the product code which would have required even more levels of management sign-off.

D. Opinion 4 – Intuitive has acted in accordance with FDA's requirements for the marketing and sale of its devices and has not unreasonably interpreted FDA's existing regulations and guidance.

1. Intuitive's marketing and sale of EndoWrist instruments with usage limits is consistent with FDA's regulatory requirements.

236. First, FDA's 510(K) clearance of EndoWrist instruments requires Intuitive to market and sell those instruments in a manner consistent with the 510(k) including the usage limits identified in the submission and ultimately cleared by FDA.

237. A manufacturer is required to market and sell its device as it was cleared by FDA.[184] FDA recognizes, however, that medical devices undergo frequent modifications to their design and materials due to many things; changes in the supply chain, continuous process improvement, or to keep pace with technological innovations that can improve how these devices work in a clinical setting. Major modifications to the device likely require premarket review by the FDA, while minor changes likely do not.[185]

238. As explained above in Section III.C.1, in accordance with 21 CFR § 807.81(a)(3), a premarket submission is required for a device that has been cleared, when a

[184] 21 CFR § 807.81(3); 21 U.S.C. § 352(o).

[185] FDA, Is A New 510(k) Required for a Modification to the Device?, https://www.fda.gov/medical-devices/premarket-notification-510k/new-510k-required-modification-device (last accessed Jan. 17, 2023).

change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process, is made, or there is a major change or modification in the intended use of the device.

239. Therefore, Intuitive must market and sell its EndoWrist instruments with the usage limits that were validated for FDA clearance, or, if it chooses to make a change or modification for the device that could significantly affect the safety or effectiveness of the device, such as extending the number of lives for which an EndoWrist may be used, Intuitive must submit a new 510(k) for the changed or modified device.

240. As discussed further below, FDA has confirmed that it believes a new 510(k) is required for modifying the usage limits on EndoWrist instruments by requiring Intuitive to submit a "catch-up" 510(k) for extending the lives of certain X/Xi instruments beyond their cleared limits.[186]

241. Additionally, FDA's view is that the EndoWrist instruments have many aspects in common with third party reprocessed single-use devices.

242. As discussed above, in its June 2015 deficiency letter to Rebotix, FDA explained that EndoWrists are not single-use devices, but because they have many "aspects in common with third party reprocessed single-use devices,"[187] Rebotix should review and provide

[186] Consistent with my experience, FDA does not take enforcement action against a company who is actively making an effort to bring a product into regulatory compliance after being informed of a non-compliance.

[187] REBOTIX171030.

the items described in FDA's guidance, "Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices."[188]

243. FDA has also explained that extending the usage limits on EndoWrist instruments requires changes to the reprocessing instructions for the device and therefore recommended (to both Intuitive and Iconocare[189]) reviewing FDA's March 2015 guidance document, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff."[190]

244. This final guidance explains recommendations for the formulation and scientific validation of reprocessing instructions for reusable medical devices. This guidance document also provides recommendations for the content and review of premarket notification submissions [510(k)], premarket approval (PMA) applications, humanitarian device exemption (HDE) applications, de *novo* requests and investigational device exemption (IDE) applications, concerning the labeling instructions for reprocessing reusable medical devices.

245. As mentioned in Section IV.B.2, this guidance also includes the recommendation that reuse life may also be addressed by validating the number of times the product can be reprocessed and reused, and providing this specification in the labeling. If the reuse life of a device is limited to a specific number of use/reprocessing cycles, the labeling

[188] REBOTIX171030. This guidance is available at https://www.fda.gov/media/71482/download (last accessed Jan. 17, 2023).

[189] Intuitive-00705778, at -5779; AHP000527, at -0528.

[190] This guidance is available at https://www.fda.gov/media/80265/download (last accessed Jan. 17, 2023).

should also describe a specific tracking method for the number of reuse cycles.[191] In my opinion, the counter that is included as part of the EndoWrist and similar devices would meet this recommendation.

2. Intuitive's cybersecurity measures are consistent with FDA expectations for devices that are vulnerable to cybersecurity threats.

246. The expert report provided by Kurt Humphrey suggests that the sole purpose for Intuitive's cybersecurity security protocols is to "thwart efforts by third-parties to reset the instrument's use counter."[192]

247. In my experience submitting recent marketing applications to FDA, cybersecurity is an area of increased focus during the review of submissions.

248. If Intuitive did not have cybersecurity measures, FDA would generate major deficiencies that would need to be resolved.

249. Specifically, FDA did in fact raise cybersecurity questions during the review of K131861. This included a request for "*Cyber and Information security*

> *You mention network communications as part of this system. There is not a separate Section addressing the CyberSecurity issues. Please review the Management of Cybersecurity Guidance issued 6/14/13 and provide information, as appropriate, on the Cybersecurity aspects of your device.'*

250. FDA specifically instructed Intuitive to review the following software guidance documents:[193]

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[191] FDA, "Reprocessing Medical Devices in health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff," at 20.

[192] Expert Report of Kurt Humphrey (Dec. 2, 2022) ¶ 60.

[193] Intuitive-00499468, at -9499-9500.

- May 11, 2005 "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", which is intended to provide information to industry regarding the documentation that FDA recommends entities include in premarket submissions for software devices, including standalone software applications and hardware-based devices that incorporate software.;[194]

- September 9, 1999 "Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices," which represents the agency's current thinking on the documentation that should be provided in premarket submissions for medical devices using off-the-shelf software;[195]

- January 11, 2002 "General Principles of Software Validation; Final Guidance for Industry and FDA Staff," which outlines general validation principles that FDA considers applicable to the validation of medical device software or software used to design, develop, or manufacture medical devices;[196]

- January 14, 2005 "Guidance for Industry, Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software," which outlines general principles that FDA considers to be applicable to software maintenance actions required to address cybersecurity vulnerabilities for networked medical devices;[197] and

[194] Available at https://www.fda.gov/media/73065/download (last accessed Jan. 17, 2023).

[195] Available at https://www.inea.com/PDF/otssguid.pdf (last accessed Jan. 17, 2023). This guidance has since been superseded by the guidance document, "Off-The-Shelf Software Use in Medical Devices," which FDA issued on September 27, 2019, available at https://www.fda.gov/media/71794/download (last accessed Jan. 17, 2023).

[196] Available at https://www.fda.gov/media/73141/download (last accessed Jan. 17, 2023).

[197] Available at https://www.fda.gov/media/72154/download (last accessed Jan. 17, 2023).

- June 14, 2013 "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff," which was developed to assist industry by identifying issues related to cybersecurity that FDA believes manufacturers should consider in the design and development of medical devices, as well as in preparing premarket submissions for those devices.[198]

251. In accordance with the June 2013 draft guidance on Management of Cybersecurity in Medical Devices, Intuitive responded with a cybersecurity hazard analysis, traceability matrix, maintenance plan, malware certification and device instructions. Additionally, they provided a cybersecurity and penetration validation protocol that evaluated the effectiveness of the company's mitigations identified as part of the cybersecurity risk analysis.

252. According to the FDA website, Medical Device Manufacturers (MDMs) are responsible for remaining vigilant about identifying risks and hazards associated with their medical devices, including risks related to cybersecurity. Both MDMs and health care delivery organizations (HDOs) are responsible for putting appropriate mitigations in place to address patient safety risks and ensure proper device performance.[199]

[198] Available at https://www.regulations.gov/document/FDA-2013-D-0616-0002 (last accessed Jan. 17, 2023). The final version of this guidance was issued on October 2, 2014, and is available at https://www.fda.gov/media/86174/download (last accessed Jan. 17, 2023).

[199] FDA, Cybersecurity, https://www.fda.gov/medical-devices/digital-health-center-excellence/cybersecurity (last accessed Jan. 17, 2023).

253. Since December 2016, FDA has issued three guidance documents related to cybersecurity, with the requirements for premarket data supporting the mitigation of cybersecurity risks increasing in each version.[200]

254. The most recent draft issued on April 8, 2022 indicates that this draft guidance replaces the 2018 draft version and is "intended to further emphasize the importance of ensuring that devices are designed securely, are designed to be capable of mitigating emerging cybersecurity risks to be mitigated throughout the [Total Product Lifecycle], and to more clearly outline the FDA's recommendations for premarket submission information to address cybersecurity concerns."[201]

3. Intuitive's internal conduct does not contradict applicable FDA regulations and guidance, nor does it negate the duty of third-party companies to comply with existing FDA regulations and guidance.

255. I understand that Intuitive told customers and FDA that the activities of these third parties were remanufacturing EndoWrist instruments in violation of FDA regulations and guidance. As explained above, this was based on a reasonable interpretation of existing FDA regulations and guidance.

[200] FDA, "Postmarket Management of Cybersecurity in Medical Devices" (Dec. 27, 2016), available at https://www.fda.gov/media/95862/download (last accessed Jan. 18, 2023); FDA, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" (Oct. 18, 2018) (draft guidance superseded by April 2022 draft guidance); FDA, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" (Apr. 8, 2022), available at https://www.fda.gov/media/119933/download (last accessed Jan. 18, 2023).

[201] FDA, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions," at 3.

256. Phillips suggests that Intuitive "addressed the question" of whether extending the usage limit of an EndoWrist instrument beyond what was cleared by FDA required submission of a 510(k) and concluded that it did not.[202] However, Phillips is wrong, and his argument misstates the underlying reality: it is FDA who determines whether 510(k) clearance is needed, and FDA has determined that 510(k) clearance is required to extend the lives of EndoWrist instruments that were cleared with prescribed usage limits.

257. Phillips points to Intuitive's determination that Intuitive, as the original equipment manufacturer, could extend lives without 510(k) clearance using a non-filing justification (NFJ).[203]

258. As discussed above in Section III.C.1, a manufacturer who has a device in commercial distribution that is about to be significantly changed or modified must submit a new 510(k). To assist manufacturers in determining whether a new 510(k) is required for a change, FDA has released certain guidance documents.[204]

259. Intuitive's decision to not file a new 510(k) for the extended lives instruments was based on the FDA guidance document, "Deciding When to Submit a 510(k) for a Change to an Existing Device."[205] This guidance applies to "manufacturers of medical devices

[202] Phillips Report ¶¶ 105–06.

[203] Ibid. ¶ 106.

[204] FDA, "Deciding When to Submit a 510(k) for a Change to an Existing Device" (Oct. 25, 2017) (originally issued Jan. 10, 1997), available at https://www.fda.gov/media/99812/download (last accessed Jan. 17, 2023); FDA, "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (Oct. 25, 2017), available at https://www.fda.gov/media/99785/download (last accessed Jan. 17, 2023).

[205] Intuitive-00705587.

subject to premarket notification requirements who intend to modify a 510(k)-cleared device (or group of devices) or other device subject to 510(k) requirements."[206] Notably, this guidance applies only to Intuitive as the manufacturer, not to remanufacturers such as Restore, Rebotix, SIS, or Iconocare Health.

260. Intuitive applied the existing guidance to the changes it, as the original equipment manufacturer, made to the EndoWrist instruments and concluded that a NFJ was appropriate and that a 510(k) submission was not necessary. This was not an unreasonable conclusion under the applicable guidance.

261. The 510(k) modifications guidance utilizes flowcharts to aid in the decision making process. The Flowcharts most applicable to this circumstance would be Flowchart A (Labeling Changes) and B (Technology, Engineering, and Performance Changes). A specific consideration in Flowchart A includes:

> *Changes in frequency or duration of use: Changes in the frequency or duration of use of a device include changes indicating that a device can or should be used more or less often, changes indicating that a device can perform a task or treat a condition in or for a different duration of time, or changes between periodic and continuous monitoring. Manufacturers should evaluate the effect such changes could have on the performance of a device, and whether such changes significantly affect the device's risk profile.*

[206] "Deciding When to Submit a 510(k) for a Change to an Existing Device," at 6.

262. However, what is more relevant to this case is that FDA determined that even Intuitive could not extend lives without seeking 510(k) clearance. FDA informed Intuitive that it would need to submit a "catch-up" 510(k) to continue marketing and selling X/Xi instruments with extended lives.[207]

263. FDA specifically informed Intuitive of the following major deficiency in an additional information request letter for K212101[208]:

> "You replied that these changes were made between K173906 and the current submission without 510(k) clearance on the basis of FDA guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device" and internally documented Non-Filing Justifications 1048606-02 (endoscope version -41), 1048620-01 (reprocessing instructions - sterilization trays), and 1048620-02 (reprocessing instructions - number of uses).
>
> However, we believe that changes to the reprocessing of your device require a 510(k). Your device falls under the Endoscope and Accessories regulation (21 CFR 876.1500). Per Appendix E of FDA's guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," a System, Surgical, Computer Controlled Instrument (product code NAY) poses a greater likelihood of microbial transmission and represents a high risk of infection if it is not adequately reprocessed. Because of the greater risks to the public health posed by these devices, 510(k) submissions should include protocols and complete test reports of the validation of the reprocessing instructions for us to evaluate substantial equivalence. Therefore, even if the endoscope validation testing was performed using similar test methodology as described in a previous 510(k) submission, the new

[207] Consistent with my experience, FDA does not take enforcement action against a company who is actively making an effort to bring a product into regulatory compliance after being informed of a non-compliance.

[208] Intuitive-00705778, at 5779–81.

> reprocessing validation information needs to be included in a 510(k) submission for FDA review.
>
> Please provide the testing and data requested below:"

264. The deficiency letter continued to list five related topics that the company should address or alternatively revise the labeling to reflect the number of uses and reprocessing instructions that have been previously cleared.

265. FDA continues on to state that "this is needed to ensure that the system instruments, cameras and sterilization trays can be used safely and effectively for the number of uses proposed in Appendix A of your reprocessing instructions."

266. It is worth noting that FDA would not require only the original equipment manufacturer, who has the complete Device History Record and access to the original validation data, to submit a 510(k) to extend the usage limits beyond the cleared limits on its own devices but then *not* require a wholly independent third party performing the same actions to comply with those same requirements for a device it did not originally manufacture. Such a double standard would be untenable.

267. Phillips suggests that because Intuitive concluded in the NFJs for extending the lives of certain X/Xi EndoWrist instruments that the extension did not "significantly change the finished device's performance or safety specifications, or intended use,"[209] it was reasonable for SIS to believe that its resetting the usage counter to increase the

[209] Phillips Report ¶¶ 105-06.

number of lives does not significantly affect the safety or effectiveness of the EndoWrist.[210] This is false.

268. Intuitive's determination that the extension of usage limits on the selected instruments did not involve any design changes that significantly affected the device's performance or safety specifications, or intended use, because Intuitive had made several incremental design changes prior to this NFJ that led the engineers to conclude that was safe to extend the lives.[211] Each of those NFJs and accompanying changes is reflected in the extended lives NFJs.[212]

269. Finally, I understand that at the point that Intuitive determined it could extend the lives on the EndoWrists (and still today), third parties did not have the capability to extend lives of X/Xi instruments. [213] Intuitive never concluded that it was safe to extend the lives of S/Si instruments, which is the activity the third parties engaged in.

v. Conclusion

270. Based on my review of the activities conducted on the Intuitive Surgical EndoWrist devices, I believe those activities meet the definition of remanufacturing as defined by FDA. Additionally, based on Agency actions as well as the descriptions provided in submitted 510(k)s, FDA considers these activities to be remanufacturing, as do the submitters of the 510(k)s who clearly describe the practice of extending the life of the instruments as

[210] Phillips Report §§ V.A.–B.

[211] Deposition of Disha Peswani (Oct. 6, 2022), Tr. 113:11-116:13.

[212] E.g. Intuitive-00552632, at -2641–51.

[213] Deposition of Stan Hamilton (Nov. 4, 2022), Tr. 14:25-15:6, 38:9-15; Deposition of Kevin May (Nov. 3, 2022), Tr. 40:21-23.

remanufacturing. I believe that these activities are permissible provided there is a valid 510(k) with supporting data to demonstrate that the remanufactured devices are substantially equivalent to the predicate Intuitive devices FDA has cleared.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: January 18, 2023

Christy Foreman

Christy Foreman, MBE

Appendices

Appendix A – Curriculum Vitae of Christy Foreman

Christy Foreman, MBE Senior Consultant

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PROFESSIONAL SUMMARY

More than 30 years experience as a biomedical engineer with over 28 years of federal experience and 22 years of FDA experience, including experience with premarket submissions (510(k)s, PMAs, IDEs, HDEs, de novos, preSubs and 513(g)s as well as cGMP/Quality Systems for medical devices.

EXPERIENCE

Biologics Consulting Group, Inc., Senior Consultant, Alexandria, VA (Apr 2018 – Present)

- Advises clients on short and long term regulatory strategies for medical devices and combination products
- Assists in the development of Quality Systems
- Prepares medical device regulatory submissions, including 510(k), PMA, HDE, RFD, 513(g), preSub, and IDE
- Represents clients in interactions with FDA; assists clients in the preparation for Advisory Panel meetings
- Provides in-house training on FDA Regulatory issues and new policy developments

Food and Drug Administration (FDA)/Center for Tobacco Products Office of Compliance and Enforcement, Associate Director for Regulatory Programs, Silver Spring, MD (Sept 2014 – Apr 2018)

- Developed foundational regulations, including manufacturing practice regulations for tobacco products Developed and established novel regulatory programs for the newest FDA center, including the No-Tobacco Sale Order Program, a novel enforcement tool for egregious violators of the Food, Drug

and Cosmetic Act
- Developed guidance documents, webinars and training programs

FDA/Center for Devices and Radiological Health (CDRH) Office of Device Evaluation (ODE), Office Director, Silver Spring, MD (Mar 2010 – Sept 2014)

- Oversaw a staff of 500+ scientists and clinicians conducting the regulatory review of applications including 510(k)s, PMAs, IDEs, HDEs, preSubs, PDPs, De Novos and 513(g)s, as well as consults for combination products in NDAs and BLAs and decided all office level appeals
- Participated in user fee negotiations with industry, implemented the user fee commitments into the regulatory review programs and implemented new legislation (FDASIA)
- Instrumental in developing regulatory improvements through the 510(k) Plan of Action

FDA/CDRH/ODE, Deputy Office Director for Science and Review Policy, Silver Spring, MD (June 2008 – Mar 2010)

- Served as the chief scientific officer for the office
- Oversaw the regulatory policies associated with 510(k), PMA, HDE, IDE, de novo and 513(g) programs as well as combination products
- Provided office-level review and sign-off for guidance documents, de novo submissions and 513(g)s

FDA/CDRH/Office of Compliance (OC)/Division of Enforcement B, Deputy Division Director, Silver Spring, MD (Dec 2002 – Dec 2008)

- Planned, organized, developed, and evaluated programmatic operations supporting the enforcement of the Federal Food, Drug and Cosmetic Act related to cardiovascular, neurology, orthopedic, physical medicine, anesthesiology and radiology devices and radiological health products such as microwaves and laser products
- Oversaw significant enforcement actions, including a seizure, several injunctions and supported criminal cases and served as an FDA expert witness for failures to comply with the Quality System Regulations Developed guidance documents for requirements for manufacturing information for PMAs

FDA/CDRH/OC/Division of Enforcement B/ Orthopedic, Physical Medicine and Anesthesiology Device Branch, Branch Chief, Silver Spring, MD (Dec 2001 – Dec 2002)

- Supervised and coordinated activities associated with regulatory actions such as seizures, injunctions, civil money penalties, recalls and warning letters
- Supervised and coordinated reviews of premarket approval applications and establishment inspections and establishment inspection reports to ensure compliance with the Quality System Regulations

FDA/CDRH/ODE/Division of Cardiovascular and Respiratory Devices/Anesthesiology and Defibrillator Devices Group, Biomedical Engineer, Silver Spring, MD (May 1996 – Dec 2001)

- Served as a scientific reviewer specializing in ventilators, oxygen therapy devices, hyperbaric chambers, CPAP devices, anesthesia workstations, pulse oximeters, multi-parameter monitors, defibrillators and cardiac resynchronization therapy
- Participated in the highly competitive FDA Leadership Development program (April 2000 – December 2001) which included leadership training as well as details to: Health Canada, Minnesota District Office, Office of Science Coordination and Communication, Office of the Commissioner and CDRH, Office of Compliance

Naval Medical Research Institute, Biomedical Engineer, Bethesda MD (June 1989 – May 1996)

- Supported military research activities in areas of thermal stress, including assessing the pathophysiology of non-freezing cold injury as well as assessing cognitive decrements induced by cold weather operations

EDUCATION

M.B.E. Biomedical Engineering, The Catholic University of America, Washington, DC (2000)

B.B.E. Biomedical Engineering, The Catholic University of America, Washington, DC (1993)

MEMBERSHIPS

Regulatory Affairs Professional Society

SELECTED RELEVANT TRAINING

AAMI GMP Quality System Requirements and Industry Practice
AAMI Deign Control Requirements and Industry Practice
AAMI Process Validation Requirements and Industry Practice AAMI CAPA Requirements and Industry Practice
Process Validation in Biotechnology Manufacturing Process Validation: Concepts and Applications
ASQ Introduction to Quality Engineering Food and Drug Law
Biostatistics
Maryland Emergency Medical Technician – B (expired)

PUBLICATIONS

- Book chapter on the regulation of hyperbaric chambers as medical devices. Hyperbaric Facility Safety: A Practical Approach 2nd Edition; 2020, edited by W.T. Workman and J. Steven Wood
- RM Kretzer, CL Foreman, JE Shuren (2010) Modernizing Device Regulation - Letter to the Editor, NEJM Jul 8;363(2):196-7; author reply 197.
- Book chapter on the regulation of hyperbaric chambers as medical devices. Hyperbaric Facility Safety: A Practical Approach; 1999, edited by W.T. Workman

SELECTED PRESENTATIONS/INVITED SPEAKER

- Instructor for RAPS European Workshop on 510(k) Basics and Working with FDA (10-11 October 2019)
- Testimony before the Subcommittee on Oversight and Investigations Committee on Energy and Commerce U.S. House of Representatives "Health Information Technologies: Administration Perspectives on Innovation and Regulation" March 21, 2013
- Presentation to the Institute of Medicine - Reviewing a 510(k), March 1, 2010
- Drug Information Association (DIA) CDRH Town Hall – June 2014
- MDMA FDA Forum: PMA/510(k) Workshop & FDA Reform – March 2014
    - Recent Trends in Device Review Process
    - Navigating Today's 510(k) Program
    - Clinical Trial Considerations
    - New World of DeNovo
    - PMA Review Considerations

    - CDRH Update
- Complex Issues in Developing Medical Devices for Pediatric Patients Affected By Rare Diseases Workshop – Engineering Considerations for Pediatric Devices, January 2014
- Transcatheter Cardiovascular Therapeutics (TCT) FDA Town Hall, Oct 2013
- DIA 2013 49th Annual Meeting: Advancing Therapeutic Innovation and Regulatory Science – June 2013
- FDA/Xavier University Medcon Conference , April 2013
- MDMA's FDA Forum – PMA/510(k) Workshop, March 2013
    - An Overview of Current Device Regulation
    - Applying Lessons Learned – Illustrations
    - CDRH Update
    - Adapting to FDA's Newest Guidance Documents
    - Clinical Trials & IDE Decisions
- FDA/Xavier University Medcon Conference , May 2011
- IN3/Gray Sheet conference – 510(k) Program, October 2010
- RAPS Annual Conference 2010 – 510(k) Program, September 2010
- CDRH 510(k) Public Workshop – Use of Predicates, Feb 2010
- Organization of Regulatory and Clinical Associates, ODE Program Updates, Nov 2008
- USPHS Leadership Development Seminar – Strategic Thinking
- AdvaMed PMA Submissions Workshops – regular presenter
- AdvaMed Annual Meetings

ADDITIONAL INFORMATION

Adjunct Faculty

Biomedical Engineering, The Catholic University of America,

Washington, DC

Medical Device Design and Regulation, 2015- Present

Appendix B – Materials Considered

Pleadings

- Complaint, Surgical Instrument Service Co., Inc. v. Intuitive Surgical, Inc., No. 3:21-cv-03496-VC (ECF 1) (May 10, 2021)
- Consolidated Amended Class Action Complaint, In re: da Vinci Surgical Robot Antitrust Litigation, Lead Case No. 3:21-cv-03825-VC (ECF 52) (Sept. 9, 2021)
- Defendant Intuitive Surgical, Inc.'s Answer, Affirmative Defense and Counterclaims, Surgical Instrument Service Co., Inc. v. Intuitive Surgical, Inc., No No. 3:21-cv-03496-VC (ECF 75) (Dec. 14, 2021)

Expert Reports

- Expert Report of Philip J. Phillips (Dec. 2, 2022) (*Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*)
- Expert Report of Dr. Robert D. Howe (Aug. 20, 2021) (*Restore Robotics LLC et al. v. Intuitive Surgical, Inc.*)
- Supplemental Expert Report of Dr. Robert D. Howe (Dec. 23, 2022) (*Restore Robotics LLC et al. v. Intuitive Surgical, Inc.*)
- Expert Report of Dr. Robert D. Howe (Dec. 2, 2022) (*Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*)
- Expert Report of Kurt Humphrey (Dec. 2, 2022) (*Surgical Instrument Service Company, Inc. v. Intuitive Surgical, Inc.*)

Deposition Transcripts and Exhibits (*SIS* and *Larkin*)

- Deposition of Clifton Parker (Oct. 25, 2022) and Exhibits
- Deposition of Disha Peswani (Oct. 6, 2022) and Exhibits
- Deposition of Grant Duque (30(b)(1)) (Nov. 8, 2022) and Exhibits
- Deposition of Grant Duque (30(b)(6)) (Nov. 8, 2022) and Exhibits
- Deposition of Greg Posdal (30(b)(1)) (Nov. 1, 2022) and Exhibits
- Deposition of Greg Posdal (30(b)(6)) (Nov. 1, 2022) and Exhibits
- Deposition of Greta Bernier (Nov. 7, 2022) and Exhibits
- Deposition of John Sampson (Nov. 3, 2022) and Exhibits
- Deposition of Jose Gonzalez (30(b)(1)) (Oct. 17, 2022) and Exhibits
- Deposition of Jose Gonzalez (30(b)(6)) (Oct. 17, 2022) and Exhibits

- Deposition of Keith Johnson (30(b)(1)) (Oct. 27, 2022) and Exhibits
- Deposition of Keith Johnson (30(b)(6)) (Oct. 27, 2022) and Exhibits
- Deposition of Kevin May (Nov. 3, 2022) and Exhibits
- Deposition of Nicky Goodson (Oct. 27, 2022) and Exhibits
- Deposition of Ricardo Estape, M.D. (Oct. 22, 2022) and Exhibits
- Deposition of Rick Ferreira (Nov. 10, 2022) and Exhibits
- Deposition of Sharathchandra "Shark" Somayaji (Nov. 4, 2022) and Exhibits
- Deposition of Stan Hamilton (Nov. 4, 2022) and Exhibits

Deposition Transcripts and Exhibits (*Restore*)

- Deposition of Clifton Parker (30(b)(6)) (May 4, 2021) and Exhibits
- Deposition of Eugene Dickens, M.D. (May 27, 2021) and Exhibits
- Deposition of Kevin May (May 6, 2021) and Exhibits
- Deposition of Kevin May (June 8, 2021) and Exhibits
- Deposition of Rafal Chudzik (June 7, 2021) and Exhibits
- Deposition of Ricardo Ferreira (June 7, 2021) and Exhibits
- Deposition of Ronald Arkin (June 9, 2021) and Exhibits

Deposition Transcripts and Exhibits (*Rebotix*)

- Deposition of David Mixner (June 10, 2021) and Exhibits
- Deposition of Edward Harrich (May 24, 2021) and Exhibits
- Deposition of Stan Hamilton (Sept. 20, 2021) and Exhibits

Produced Documents

- ACG000006
- AHP000369
- AHP000373
- AHP000404
- AHP000525
- AHP000527
- AHP000658
- AHP000706
- AHP000708
- AHP000729
- AHP000732
- AHP000803
- AHP000832
- AHP000928
- AHP000939
- AHP002062
- AHP002130
- AHP002395
- AHP002448
- AHP002623
- AHP002680
- AHP003709
- AHP005099
- BPI000331

- Intuitive-00481165
- Intuitive-00481167
- Intuitive-00481176
- Intuitive-00491017
- Intuitive-00492705
- Intuitive-00493504
- Intuitive-00493612
- Intuitive-00499468
- Intuitive-00515501
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- Intuitive-00691660
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- REBOTIX155894
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- REBOTIX169588
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- REBOTIX170053
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- REBOTIX171030
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- REBOTIX175468
- REBOTIX175710

- Restore-00001248
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- Restore-00117692
- Restore-00122811
- Restore-00131763
- Restore-00132592
- Restore-00134924
- SIS357813
- VMC-00018032

Publications

- "Device Ownership Should Not Be Criterion for Regulation of Reprocessors," The Gray Sheet, Vol. 24, No. 27 (July 6, 1998)
- FDA, "Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended – Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices" (May 1, 2006), available at https://www.fda.gov/media/71187/download (last accessed Jan. 17, 2023)
- FDA, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff" (June 14, 2013), available at https://www.regulations.gov/document/FDA-2013-D-0616-0002 (last accessed Jan. 17, 2023)
- FDA, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff" (Oct. 2, 2014), available at https://www.fda.gov/media/86174/download (last accessed Jan. 17, 2023)

- FDA, "CPG § 300.500 (Reprocessing of Single Use Devices)", available at: https://www.fda.gov/media/71769/download (last accessed Jan. 17, 2023)
- FDA, "Deciding When to Submit a 510(k) for a Change to an Existing Device" (Oct. 25, 2017) (originally issued Jan. 10, 1997), available at https://www.fda.gov/media/99812/download (last accessed Jan. 17, 2023)
- FDA, "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (Oct. 25, 2017), available at https://www.fda.gov/media/99785/download (last accessed Jan. 17, 2023)
- FDA, "Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications)" (Aug. 30, 2019) (originally issued Mar. 28, 2012), available at https://www.fda.gov/media/99769/download (last accessed Jan. 17, 2023)
- FDA, "General Principles of Software Validation; Final Guidance for Industry and FDA Staff" (Jan. 11, 2002), available at https://www.fda.gov/media/73141/download (last accessed Jan. 17, 2023)
- FDA, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005), available at https://www.fda.gov/media/73065/download (last accessed Jan. 17, 2023)
- FDA, "Guidance for Industry, Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software" (Jan. 14, 2005), available at https://www.fda.gov/media/72154/download (last accessed Jan. 17, 2023)
- FDA, "Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices" (Sept. 9, 1999), available at https://www.inea.com/PDF/otssguid (last accessed Jan. 17, 2023)
- FDA, K210478 510(k) Summary, available at: https://www.accessdata.fda.gov/cdrh_docs/pdf21/K210478 (last accessed Jan. 17, 2023)
- FDA, "Format for Traditional and Abbreviated 510(k)s" (Sept. 13, 2019) (originally issued Aug. 12, 2005), available at https://www.fda.gov/media/130647/download (last accessed Jan. 17, 2023)
- FDA, "Medical Device Classification Product Codes" (Apr. 11, 2013), available at https://www.fda.gov/media/82781/download (last accessed Jan. 17, 2023)
- FDA, "Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices" (Sept. 25, 2006) (originally issued June 1, 2004), available at https://www.fda.gov/media/71482/download (last accessed Jan. 17, 2023)
- FDA, "Off-The-Shelf Software Use in Medical Devices" (Sept. 27, 2019), available at https://www.fda.gov/media/71794/download (last accessed Jan. 17, 2023)

- FDA, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance" (Mar. 17, 2015), available at https://www.fda.gov/media/80265/download (last accessed Jan. 17, 2023)
- FDA, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" (July 28, 2014), available at https://www.fda.gov/media/82395/download (last accessed Jan. 17, 2023)
- FDA, "White Paper: Evaluating Whether Activities are Servicing or Remanufacturing" (December 2018), available at https://www.fda.gov/media/117238/download (last accessed Jan. 17, 2023)
- FDA Report on the Quality, Safety and Effectiveness of Servicing of Medical Devices (May 2018), available at https://www.fda.gov/media/113431/download (last accessed Jan. 17, 2023)

Other Documents

- Code of Federal Regulations
  - 21 CFR § 10
  - 21 CFR § 801
  - 21 CFR § 803
  - 21 CFR § 806
  - 21 CFR § 807
  - 21 CFR § 814
  - 21 CFR § 820
  - 21 CFR § 821
  - 21 CFR § 860
  - 21 CFR § 862
  - 21 CFR § 864
  - 21 CFR § 876
  - 21 CFR § 878
- Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*)
- Federal Register

  - 58 Fed. Reg. 61952 (Nov. 23, 1993)
  - 61 Fed Reg. 52602 (Oct. 7, 1996)
  - 62 Fed. Reg. 8961 (Feb. 27, 1997)
  - 63 Fed. Reg. 67076 (Dec. 4, 1998)
- H.R. Rept. 94-853, at 15 (Feb. 29, 1976)
- Letter from Counsel to the Association of Medical Device Reprocessors to FDA (Mar. 23, 1998)
- Letter from Johnson & Johnson to FDA (Mar. 23, 1998)
- Letter from Ronald E. Eames, President and Managing Director, Medical Devices Services, Inc. to FDA (Mar. 21, 2000)
- Medical Device User Fee and Modernization Act of 2002, PL 107–250, October 26, 2002, 116 Stat 1588.
- Plaintiff Rebotix Repair, LLC's Disclosure Pursuant to Fed. R. Civ. P. 26(a)(2)(c) (Stan Hamilton (Aug. 30, 2021) (*Rebotix Repair LLC v. Intuitive Surgical, Inc.*)
- Prepared Testimony of Vern Feltner, President of Alliance Medical Corporation, on behalf of the Association of Medical Device Reprocessors (June 27, 2000)

Appendix C - QSM and NAY Premarket Submissions

Device Name	Applicant	510(K) Number	Decision Date
Da Vinci X Surgical System (Is4200), Da Vinci Xi Surgical System (Is4000)	Intuitive Surgical, Inc	K223080	11/22/2022
Da Vinci Firefly Imaging System	Intuitive Surgical Inc.	K222827	10/20/2022
8mm Monopolar Curved Scissors	Iconocare Health	K210478	09/30/2022
Da Vinci X/Xi (Is4200/Is4000) 8mm Reusable Instruments	Intuitive Surgical, Inc.	K214095	08/15/2022
Senhance Surgical System	Asensus Surgical, Inc.	K220889	05/27/2022
Da Vinci Fluorescence Imaging Vision System, Da Vinci Firefly Imaging System	Intuitive Surgical, Inc.	K213710	02/17/2022
8mm Monopolar Curved Scissors	Intuitive Surgical, Inc.	K220023	01/31/2022
8 Mm Sureform 30 Curved-Tip Stapler, 8 Mm Sureform 30 Stapler, Sureform 30 Reloads	Intuitive Surgical, Inc.	K211997	12/10/2021
Da Vinci Sp Firefly Imaging System	Intuitive Surgical, Inc.	K212101	11/23/2021
Da Vinci Sp Surgical System	Intuitive Surgical, Inc.	K212747	09/29/2021
Handx	Human Xtensions Ltd.	K212214	09/13/2021
Senhance Surgical System	Asensus Surgical, Inc.	K212054	08/30/2021
Da Vinci Xi Surgical System (Is4000), Da Vinci X Surgical System (Is4200)	Intuitive Surgical, Inc.	K211784	08/06/2021
Senhance Surgical System	Asensus Surgical, Inc.	K211325	07/27/2021
Da Vinci Sp Surgical System (Sp1098)	Intuitive Surgical, Inc.	K211316	07/23/2021
Stitchkit	Origami Surgical Inc .	K211792	07/16/2021
Da Vinci Sp Surgical System (Sp1098)	Intuitive Surgical, Inc.	K211595	06/23/2021
Da Vinci Fluorescence Imaging Vision System, Da Vinci Firefly Imaging System	Intuitive Surgical, Inc.	K210918	04/26/2021
Senhance Surgical System	TransEnterix, Inc.	K202166	03/02/2021
Stitchkit Combo	Origami Surgical	K202950	02/23/2021
Da Vinci S/Si (Is2000/Is3000) 5mm And 8mm Reusable Instruments, Da Vinci Xi/X (Is4000/Is4200) 8mm Reusable Instruments	Intuitive Surgical, Inc.	K203632	02/10/2021
Soloasisst Ii, Voice Control	AKTORmed GmbH	K200473	12/22/2020
Da Vinci Sp Surgical System	Intuitive Surgical, Inc.	K202968	12/22/2020

Device Name	Applicant	510(K) Number	Decision Date
Da Vinci Xi Surgical System (Is4000), Da Vinci X Surgical System (Is4200)	Intuitive Surgical, Inc.	K202834	12/10/2020
Da Vinci Sp Surgical System, Model Sp1098, Endowrist Sp Instruments, And Accessories	Intuitive Surgical, Inc.	K202571	11/12/2020
Da Vinci Sp Surgical System	Intuitive Surgical Inc.	K192717	09/28/2020
Da Vinci Xi Surgical System, Da Vinci X Surgical System	Intuitive Surgical	K192803	04/29/2020
Da Vinci X And Xi Surgical System	Intuitive Surgical, Inc	K183086	03/31/2020
Senhance Surgical System	TransEnterix, Inc.	K200049	03/09/2020
Da Vinci Xi Surgical System, Da Vinci X Surgical System	Intuitive Surgical	K191529	02/06/2020
Senhance Surgical System	TransEnterix, Inc.	K192877	11/22/2019
E-100 Electrosurgical Generator, Synchroseal	Intuitive Surgical, Inc.	K191280	11/14/2019
Da Vinci X/Xi 8mm Endoscope Plus, 0, Da Vinci X/Xi 8mm Endoscope Plus, 30	Intuitive Surgical	K191736	07/26/2019
Stitchkit	Origami Surgical	K191317	07/12/2019
Sureform 45 Curved Tip, Sureform 45 Gray Reload	Intuitive Surgical, Inc.	K190999	07/12/2019
Senhance Surgical System	TransEnterix Inc.	K191482	07/11/2019
Da Vinci Sp Surgical System, Endowrist Sp Instruments, And Accessories	Intuitive Surgical, Inc.	K182371	03/14/2019
Sureform 45, Sureform 45 Reloads	Intuitive Surgical	K183224	01/18/2019
Senhance Ultrasonic System	TransEnterix, Inc.	K182421	01/11/2019
Intuitive Surgical Vessel Sealer Extend	Intuitive Surgical, Inc.	K183107	12/11/2018
Senhance Surgical System	TransEnterix, Inc.	K183098	12/06/2018
Da Vinci Xi Surgical System, Da Vinci X Surgical System	Intuitive Surgical, Inc	K182140	10/24/2018
Senhance Surgical System	TransEnterix, Inc.	K181517	10/09/2018
Soloassist Ii	AKTORmed GmbH	K171947	09/21/2018
Endowrist Mercury Bipolar Grasper	Intuitive Surgical, Inc.	K180351	08/07/2018
Da Vinci Xi Surgical System, Da Vinci X Surgical System	Intuitive Surgical, Inc.	K173585	07/19/2018
Sureform 60 And Sureform 60 Reloads	Intuitive Surgical	K173721	07/05/2018
Da Vinci Sp Surgical System, Endowrist Sp Instruments, And Accessories	Intuitive Surgical, Inc.	K173906	05/31/2018
Endowrist 5mm Thoracic Grasper	Intuitive Surgical, Inc.	K173415	05/31/2018

Device Name	Applicant	510(K) Number	Decision Date
Transenterix Senhance Surgical System	TransEnterix, Inc.	K180163	05/25/2018
Stitchkit V-Loc 90, Stitchkit V-Loc 180, Stitchkit Quill Pdo	Origami Surgical LLC	K173874	05/04/2018
Intuitive Surgical Endowrist Vessel Sealer Extend	Intuitive Surgical, Inc.	K173337	04/26/2018
Da Vinci Xi Surgical System, Da Vinci X Surgical System	Intuitive Surgical, Inc	K173842	04/23/2018
8mm Monopolar Curved Scissors	Intuitive Surgical, Inc	K180033	04/06/2018
Hx Device	Human Extension Ltd.	K173919	03/20/2018
Da Vinci Xi Surgical System; Da Vinci X Surgical System	Intuitive Surgical, Inc.	K172643	01/31/2018
Senhance Surgical Robotic System	TransEnterix, Inc.	K171120	10/13/2017
Da Vinci S/Si Endoscopes, Da Vinci Xi Endoscopes	Intuitive Surgical, Inc.	K170641	09/21/2017
Is4000 Stapler 45 Instrument And Its Reusable Accessories, Is4000 Endowrist Stapler 30 Instrument, Is3000 Stapler 45 Instrument And Its Reusable Accessories	Intuitive Surgical, Inc.	K170879	09/21/2017
Da Vinci Xi Surgical System	Intuitive Surgical, Inc	K171632	09/19/2017
Da Vinci Si Single-Site Instruments And Accessories, Da Vinci Xi Single-Site Instruments And Accessories	Intuitive Surgical, Inc.	K170875	09/12/2017
Da Vinci S/Si Endowrist Instruments And Accessories, Harmonic Ace Curved Shears (5mm & 8mm)	Intuitive Surgical, Inc.	K170644	09/11/2017
Da Vinci Xi Endowrist Instruments And Accessories	Intuitive Surgical, Inc.	K170645	09/11/2017
Da Vinci Xi Surgical System, Da Vinci Si Surgical System, Da Vinci X Surgical System	Intuitive Surgical, Inc	K171699	07/28/2017
Da Vinci Xi 8mm Endoscope, 0 Degree, Da Vinci Xi 8mm Endoscope, 30 Degree	Intuitive Surgical, Inc.	K171426	06/13/2017
Da Vinci Xi Surgical System	Intuitive Surgical, Inc	K170713	06/13/2017
Endowrist Stapler 45 System And Stapler 45 Reloads	Intuitive Surgical, Inc.	K171388	05/31/2017
Da Vinci X Surgical System	Intuitive Surgical, Inc.	K171294	05/26/2017
Endowrist Vessel Sealer, 8 Mm Harmonic Ace Curved Shears, Da Vinci Single-Site Instruments And Accessories	Intuitive Surgical, Inc.	K170865	04/21/2017
Endowrist Stapler 45 Instrument, Endowrist Stapler 45 Reloads, Endowrist Stapler 30 Instrument, Endowrist Stapler 30 Reloads	Intuitive Surgical, Inc.	K170508	03/10/2017
Endowrist Suction Irrigator	Intuitive Surgical, Inc.	K162973	02/06/2017
Da Vinci Xi Surgical System	Intuitive Surgical, Inc.	K161178	01/19/2017

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Da Vinci Xi 12 – 8 Mm Reducer	Intuitive Surgical, Inc.	K162411	09/21/2016
Da Vinci Xi Surgical System	INTUITIVE SURGICAL, INC.	K153276	08/07/2016
Da Vinci Xi Surgical System	Intuitive Surgical, Inc.	K161271	07/11/2016
Da Vinci Xi Surgical System	INTUITIVE SURGICAL	K152892	04/29/2016
Da Vinci Surgical System, Model Is4000	INTUITIVE SURGICAL, INC.	K152578	03/30/2016
Da Vinci Single-Site Instrument And Accessories	INTUITIVE SURGICAL, INC.	K152448	03/09/2016
Is4000 Stapler 30 Instrument And Stapler 30 Reloads	INTUITIVE SURGICAL, INC.	K152421	03/04/2016
Da Vinci Xi Surgical System	Intuitive Surgical, Inc.	K151794	01/15/2016
Is4000 Da Vinci Endowrist Instruments	INTUITIVE SURGICAL, INC.	K150284	05/15/2015
Is4000 Small Clip Applier, Is4000 Long Bipolar Forceps	INTUITIVE SURGICAL, INC.	K150837	04/29/2015
Is4000 8mm Harmonic Ace Curved Shears	INTUITIVE SURGICAL, INC.	K143132	04/02/2015
Stitchkit	ORIGAMI SURGICAL LLC	K142639	12/16/2014
12 Mm Endoscopes And Accessories	INTUITIVE SURGICAL, INC.	K142683	12/10/2014
12 Mm & Stapler Bladeless Obturators	INTUITIVE SURGICAL, INC.	K143217	12/03/2014
Single-Site Wristed Needle Driver	INTUITIVE SURGICAL	K141075	09/26/2014
Da Vinvi Surgical System	INTUITIVE SURGICAL, INC.	K123329	09/17/2014
Da Vinci Firefly Imaging System	INTUITIVE SURGICAL, INC.	K141077	08/12/2014
Endowrist Stapler 45 And Stapler 45 Reloads	INTUITIVE SURGICAL, INC.	K140553	07/25/2014
Endowrist Vessel Sealer	INTUITIVE SURGICAL, INC.	K140189	06/05/2014
Single-Site Port	INTUITIVE SURGICAL, INC.	K133203	05/09/2014
Da Vinci Sp Surgical System, Endowrist Sp Instruments, And Accessories	INTUITIVE SURGICAL, INC.	K131962	04/17/2014
Da Vinci Surgical System, Endowrist Instruments And Accessories	INTUITIVE SURGICAL, INC.	K131861	03/28/2014
Stitchkit	ORIGAMI SURGICAL LLC	K123811	09/05/2013
Endowrist One Vessel Sealer	INTUITIVE SURGICAL, INC.	K130266	08/29/2013
Da Vinci Single-Site Instruments And Accessories	INTUITIVE SURGICAL, INC.	K122532	07/30/2013
Da Vinci Single-Site Permanent Cautery Hook	INTUITIVE SURGICAL, INC.	K130726	06/07/2013

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Connect For Da Vinci Surgical System(S)	INTUITIVE SURGICAL, INC.	K123840	02/14/2013
Intuitive Surgical Da Vinci Si Surgical System Smartpedals	INTUITIVE SURGICAL, INC.	K123463	12/03/2012
Intuitive Surgical Onsite For Da Vinci Surgical Systems	INTUITIVE SURGICAL, INC.	K121921	10/25/2012
Endowrist Stapler System	INTUITIVE SURGICAL, INC.	K113706	10/17/2012
Single-Site Medium-Large Clip Applier, Single-Site Cadiere Grasper, Single-Site Fundus Grasper, Single-Site Crocodile	INTUITIVE SURGICAL, INC.	K120215	04/30/2012
Endowrist One Vessel Sealer	INTUITIVE SURGICAL, INC.	K110639	12/28/2011
Intutive Surgical Da Vinci Single Site Instruments And Accessories	INTUITIVE SURGICAL, INC.	K112208	12/08/2011
Monopolar Curved Scissors Tip Cover Accessory	INTUITIVE SURGICAL, INC.	K112263	10/07/2011
5mm/8mm Harmonic Ace(Tm) Curved Shears, Disposable Harmonic Ace(Tm) Insert, Disposable Harmonic(Tm) Curved Shears Insert	INTUITIVE SURGICAL, INC.	K112584	09/29/2011
Endowrist One Suction/Irrigator	INTUITIVE SURGICAL, INC.	K110451	08/26/2011
Intuitive Surgical Da Vinci S Surgical System With Da Vinci Connect & Da Vinci Onsite, Model Is2000	INTUITIVE SURGICAL, INC.	K101581	04/08/2011
5mm Flared Cannula Model 420262, 8mm Flared Cannula Model 420319	INTUITIVE SURGICAL, INC.	K101743	02/04/2011
Da Vinci Fluorescence Imaging Vision System, Model Ff 100	INTUITIVE SURGICAL, INC.	K101077	02/04/2011
5 Mm Harmonic Ace Instrument (Used With Da Vinci Is1200 & Is2000/Is3000 System)	INTUITIVE SURGICAL, INC.	K093217	01/21/2010
Intuitive Surgical Endoscopic Instrument Control Systems, Models Is1200, Is2000 And Is3000	INTUITIVE SURGICAL, INC.	K090993	12/16/2009
Intuitive Surgical Endowrist One Hot Shears Instrument	INTUITIVE SURGICAL, INC.	K082497	05/07/2009
Intuitive Surgical Da Vinci Si Surgical System: Model Is3000	INTUITIVE SURGICAL, INC.	K081137	02/18/2009
Intuitive Surgical Da Vinci S Surgical System, Model Is2000, With Da Vinci Connect And Onsite	INTUITIVE SURGICAL, INC.	K081207	12/19/2008
Intuitive Surgical Da Vinci Endoscopic Instruments And Control System And Endowrist Stabilizer	INTUITIVE SURGICAL, INC.	K080291	03/19/2008
Intuitive Surgical Da Vinci Surgical System And Endoscopic Instruments And Endowrist Cardiac Probe Grasper	INTUITIVE SURGICAL, INC.	K070947	02/14/2008
Intuitive Surgical Da Vinci And Da Vinci S Surgical System And Endoscopic Instruments And Endowrist Introducer	INTUITIVE SURGICAL, INC.	K072627	02/07/2008

Device Name	Applicant	510(K) Number	Decision Date
Da Vinci S Surgical System-V1.1, Model Is2000	INTUITIVE SURGICAL, INC.	K063220	12/01/2006
Intuitive Surgical Endowrist Pk Dissecting Forceps, Models 400214 & 420214	INTUITIVE SURGICAL, INC.	K061260	05/18/2006
Intuitive Surgical Endowrist Stabilizer, Model 420182	INTUITIVE SURGICAL, INC.	K060391	04/10/2006
Modification To Intuitive Surgical Da Vinci Surgical System And Endoscopic Instruments	INTUITIVE SURGICAL, INC.	K050802	06/29/2005
Intuitive Surgical Da Vinci Surgical System, Model Is2000	INTUITIVE SURGICAL, INC.	K050369	04/29/2005
Modification To Intuitive Surgical Da Vinci Surgical System And Endoscopic Instruments	INTUITIVE SURGICAL, INC.	K043288	03/03/2005
Intuitive Surgical Monopolar Curved Scissors, Model 400179; Tip Cover Accessory, Model 400180	INTUITIVE SURGICAL, INC.	K050005	01/25/2005
Intuitive Surgical Da Vinci Surgical System And Endoscopic Instruments, Models Is1200 & Is1000	INTUITIVE SURGICAL, INC.	K043153	12/15/2004
Intuitive Surgical Harmonic Curved Shears Instrument	INTUITIVE SURGICAL, INC.	K042855	11/12/2004
Intuitive Surgical Da Vinci Endoscopic Instrument Control System And Endoscopic Instruments	INTUITIVE SURGICAL, INC.	K040237	07/07/2004
Intuitive Surgical Endopass Endoscopic Delivery Instrument, Model P/N 400170	INTUITIVE SURGICAL, INC.	K040948	05/05/2004
Bipolar Grasper And Bipolar Scissors For The Zeus Microwrist Surgical System	COMPUTER MOTION, INC.	K030578	06/24/2003
Intuitive Surgical Endoscopic Instrument Control System & Endoscopic Instruments, Model Da Vinci Isi 1000/1200	INTUITIVE SURGICAL, INC.	K022574	11/12/2002
Zeus Microwrist Robotic Surgical System And Accessories	COMPUTER MOTION, INC.	K021152	09/24/2002
Intuitive Surgical Da Vinci Surgical System, Model Is1000	INTUITIVE SURGICAL, INC.	K021036	06/26/2002
Intuitive Surgical Bipolar Forceps	INTUITIVE SURGICAL, INC.	K012833	11/16/2001
Intuitive Surgical Ultrasonic Shears	INTUITIVE SURGICAL, INC.	K011281	07/24/2001
Intuitive Surgical Da Vinci Surgical System, Model Isi 1000	INTUITIVE SURGICAL, INC.	K011002	05/30/2001
Intuitive Surgical Da Vinci Endoscopic Control System	INTUITIVE SURGICAL, INC.	K002489	03/02/2001
Intuitive Surgical Endoscopic Instruments, Intuitive Surgical Endoscopic Instrument Control System	INTUITIVE SURGICAL, INC.	K990144	07/11/2000